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Policy and Institutional Factors and the Distribution of Economic Benefits and Risk from the Adoption of Insect Resistant (Bt) Cotton in West Africa

José Falck-Zepeda*, Daniela Horna**, Patricia Zambrano*** and Melinda Smale****

Abstract: Some countries in West Africa are considering the potential adoption of insect resistant cotton. Burkina Faso has already approved commercial cultivation of this technology. This paper presents the results of a socio economic impact assessment of the potential adoption of insect resistant cotton in West Africa using an augmented economic surplus model to consider risk and parameter uncertainty. Model considers changes in parameters such as technology fees, regulatory lags, and adoption patterns. Results show these are important in shaping the average response but also its distribution. Countries in West Africa definitively loose from not adopting Bt cotton. Adoption with reduced or no technology fees gathered the most gains to producers and for society as a whole. The paper develops a discussion of the potential policy and institutional factors affecting adoption outcomes.

Keywords: Bt Cotton, Economic Surplus Model; West Africa, Benefits, Risk; Biotechnology

Introduction

Burkina Faso approved in 2007 the commercial cultivation of genetically modified Bt (*Bacillus thuringiensis* kurstaki) cotton. The main trait of Bt cotton is the expression of insect resistance to specific lepidopteran insects. Cotton growers in West Africa (WA) and other regions of Africa may gain access to Bt cotton as this product is undergoing biosafety evaluation in Kenya and Uganda, and has been approved for commercial

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cultivation in South Africa. Yet, the potential adoption of Bt cotton by West African nations has generated conflicting points of view about the uncertain impacts of genetically modified technologies on the economy and the environment.

In this paper, we describe an *ex ante* assessment of the potential adoption impact of Bt cotton by major cotton-producing countries in West Africa. These countries include Benin, Burkina Faso, Mali, Senegal and Togo. Recognizing the risk and uncertainty associated with the technology and the limitations of existing data, we expand the economic surplus model with a stochastic analysis. We develop five scenarios to highlight the effects of policies and institutional factors on the distribution of benefits and risks that lend insights into policy and institutional issues that are critical for the proper deployment of crop biotechnology in West Africa.

To ensure proper discussion of policies and institutional issues, we first review background information and previous studies related to the economic impact of Bt cotton at the industry level in West Africa. Then, we briefly describe the model, scenarios and findings.[1] Finally, we discuss institutional and policy issues related to the potential adoption of Bt cotton in order to address the potential limitations that may arise from the adoption and use of Bt cotton technology in Africa.

Cotton production has significant implications for the livelihood of resource poor farmers in West Africa. Approximately 1-2 million smallholder farmers produce most of the cotton in the region (SWAC Secretariat OECD 2005). Cotton production creates significant direct and indirect employment opportunities in the region. Smallholder cotton producers in West Africa are usually well diversified in terms of crops, employing mostly household labour for their cultivation.

West African governments view cotton as an alternative cash crop for smallholder producers that can support income creation and that can generate hard currency from exports. West Africa currently accounts for approximately 10 per cent of world cotton exports and is the third largest cotton producer in the world. (*FAO Statistics* 2005). For a long time, West Africa as a region has had a comparative advantage over other cotton producing countries in terms of lower production costs, high quality fiber, and a solid institutional infrastructure (Baffes 2004).

Cotton responds well to environmental conditions in the region, characterized by frequent droughts and variable rainfall. Insect damage, however, limits cotton production in West Africa. Without chemical control, yield damage from lepidopteran insects[2] can vary from 23 to 34 per cent (Oerke, *et al.* 1995). Lepidopteran and other insect damage to cotton production, coupled with increased resistance to commonly used pesticides, may help explain the loss in the region's competitive advantage. (Martin *et al.* 2002). Efforts to control lepidopteran damage add to approximately 194 million dollars annually with increasingly lower success (CAB International (2001).

Ajayi *et al.* (2002) reports that cotton yields have declined in West Africa with a concurrent increases in pesticide use partly due to increased resistance of pests, such as cotton bollworm. Integrated pest management practices have been proposed to improve pest control, reduce pesticide applications and reduce farmers' costs (Ochout et al. 1998). Yet, these practices have not been widely adopted in the region (Silvie *et al.* 2001). Bt cotton is an alternative for controlling target lepidopteran pests and thus may contribute to cotton productivity improvements in West Africa. The need exists for credible information related to the potential impact of Bt cotton and other modern biotechnologies. Economic practitioners have used economic surplus models in both *ex ante* and *ex post* situations to provide decision makers with robust information about adoption impacts.

Background on Bt Cotton

The first gene used in Bt cotton (commercial name Bollgard™), known as *Cry1Ac*, was developed by Monsanto in the 1980s from the soil micro-organism, *Bacillus thuringiensis* kurstaki. Scientists long know that this microorganism produces a protein that is toxic to a limited number of Lepidopteran insects when ingested. The range of control of the technology has been extended through the introduction of two or more Bt genes inserted into the plant or by the expression of new chemistries. Bt cotton was first sold in the United States in 1996 and was developed through a strategic alliance between Monsanto and the dominant U.S. seed cotton firm, Delta and Pineland (D&PL).

Bt cotton has been approved for commercial cultivation in nine countries including Argentina, Australia, Brazil, Colombia, China, India, Mexico, South Africa and United States (James 2007). In these countries, the developer has either entered into licensing agreements with local seed companies or as in India and China has developed and directly commercialized the innovation. In all countries, the innovator has charged producers a fee for using the technology beyond the regular seed cost. The ability to charge a technology fee or premium is possible due to the temporary monopoly granted by intellectual property protection and/or the fact that the innovator may be the sole supplier of this particular product.

From the standpoint of the private sector, West Africa may be an attractive sizable market, provided there are proper IP protection and market penetration. Table 1 presents gross income estimates of the value of the technology fee under varying adoption assumptions. At an expected level of 20 per cent adoption for the whole region, the market value of the Bt technology fee runs from 8.5 and 45 million dollars for the $15 and $80 per hectare technology fee. If we add the combined potential markets of Burkina Faso, Benin, Mali, Côte d'Ivoire, and Togo, the value of the technology fee ranges from 4.6 to 24.5 million dollars annually. This may represent an attractive market for a technology whose R&D costs have been paid elsewhere through deployment in other countries. So far, the apparent release plans are for the technology to be commercialized in close collaboration with national research organizations and thus there may not be a technology fee charged to farmers. This may change in the course of transferring the technology to producers in Burkina Faso and other countries in West Africa.

Literature on Bt Cotton Impact Assessment in West Africa

A significant share of the existing adoption impact assessment literature is on Bt cotton. Of the published peer reviewed literature, the largest share examines the impact of farmer adoption (Smale *et al.* 2006b). Of the published studies, only three address the potential economic impact of Bt cotton in West Africa. Cabanilla *et al.* (2003) estimated aggregate *ex ante* benefits from the adoption of Bt cotton in West Africa by utilizing a linear programming model to derive benefits for a representative farm resulting from estimating optimal allocations for land, output, profit and whole farm income. Linear programming estimates used detailed field studies data to estimate farm level outcomes, which where aggregated to the national level. Authors estimate that aggregate benefits annually accruing to farmers were $68 million in Mali, $41 million in Burkina Faso, $53 million in Benin, $39 million in Côte d'Ivoire and $8 million in Senegal. In summary, Cabanilla et al. (2003) showed that the region would forego significant benefits from not adopting Bt cotton.

Table 1. Annual Gross Income to Gene/Germplasm Innovator from Charging a Per Hectare Technology Fee Assuming 100%, 60% and 20% Adoption Levels in West Africa

Country	Income from technology fee with 100% adoption		Income from technology fee with 60% adoption		Income from technology fee with 20% adoption	
	Tech fee= 15 ($/ha)	Tech fee= 80 ($/ha)	Tech fee= 15 ($/ha)	Tech fee= 80 ($/ha)	Tech fee= 15 ($/ha)	Tech fee= 80 ($/ha)
Benin*	5.4	29.1	3.3	17.4	1.1	5.8
Burkina Faso*	4.8	25.8	2.9	15.5	1	5.2
Mali*	6	32.2	3.6	19.3	1.2	6.4
Senegal*	0.4	2.4	0.3	1.4	0.1	0.5
Togo	2.3	12	1.4	7.2	0.5	2.4
Sub-total countries in study	18.9	101.5	11.5	60.8	3.9	20.3
Cameroon	3	16.2	1.8	9.7	0.6	3.2
C. African Rep.	0.5	2.7	0.3	1.6	0.1	0.5
Chad	4.4	23.4	2.6	14	0.9	4.7
Congo, D.R.	1	5.5	0.6	3.3	0.2	1.1
Côte d'Ivoire*	4.5	23.9	2.7	14.3	0.9	4.8
Gambia	0	0.1	0	0	0	0
Ghana	0.5	2.8	0.3	1.7	0.1	0.1
Guinea	0.7	3.7	0.4	2.2	0.1	0.7
Guinea-Bissau	0.1	0.3	0	0.2	0	0.1
Mauritania	0	0.2	0	0.1	0	0
Nigeria	8.5	45.1	5.1	27.1	1.7	9
Sub-total rest of West Africa	23.2	123.9	13.8	74.2	4.6	24.2
Total West Africa	42.3	225.3	25.4	135.2	8.5	45.1

Note: Based on FAOSTAT data on area planted in West Africa.

Elbeheri and Macdonald (2005) utilize a multi-region general equilibrium model to estimate the likely impacts – especially on trade-of adoption and non-adoption of Bt cotton in West Africa. In the case of non-adoption in West and Central Africa, but with adoption in other countries, the authors estimate that social welfare in the region will decrease by US$ 88 million annually. In contrast, adoption of Bt cotton technology increases social welfare, as the change in producer surplus induced by the expansion in cotton supply is larger than the expected concomitant cotton price reduction.

Vitale *et al.* (2007) examines the potential adoption of Bt cotton and maize in West Africa with an emphasis in Mali. Dual cultivation of maize and cotton is a common production system in Mali. The authors make use of confined and large-scale field trials in Burkina Faso to draw performance data that was used in their simulations. The paper use an economic surplus model augmented with a farmer decision-making component. Adoption decisions are thus endogenous to the model. Due to the nature of the markets for cotton and maize, simulation results diverge significantly. In the case of cotton, with a strong export market, farmers capture a large share of benefits. In contrast, as maize is mainly a subsistence crop, consumers capture the larger share of economic surplus generated from the adoption of Bt maize. Estimates show that aggregate benefits from Bt cotton adoption would surpass those associated with Bt maize by $10.3 million per year.

Many *ex ante* (and *ex post*) assessments of GM crops use the approach presented in Falck-Zepeda *et al.* (2000a, 2000b) as foundation for their implementation. The approach considers of an adjustment to the standard economic surplus model described by Alston et al. (1995),that accounts for temporary monopolies derived from the intellectual property protection endowed to most GM crops (Moschini and Lapan 1997). A major disadvantage of the economic surplus approach is that it relies on underlying parameters. In those cases where there is very little or no information or where information is not reliable, usually the situation with *ex ante* assessments, estimates may not be as robust as desired. Impact assessment practitioners may gather information from other countries (such as Vitale *et al.* 2007 or Cabanilla *et al.* 2005) or may elicit information from local experts. Furthermore, conventional economic surplus models do not incorporate risk or uncertainty typical of agricultural production and smallholder producers in developing countries.

We now discuss a modification to the conventional economic surplus model that incorporates a stochastic component allowing the examination of risk arising from the adoption of Bt cotton in West Africa. One of the advantages of using a stochastic simulation is the ability to evaluate the variability of simulation outcome and the risk. We present five scenarios that will examine a portfolio of policy and institutional factors issues relevant in West Africa.

Studies examining Bt cotton adoption in countries such as South Africa (Gouse *et al.*2005), Mexico (Traxler *et al.* 2003) and Argentina (Qaim and Janvry 2005), demonstrate the need to examine institutional and policy issues as they may have an impact on the level and distribution of economic benefits accruing to farmers. Institutional and policy issues include legal frameworks, credit availability, production contracts, the technology premium fee level, and the degree to which seed, input and product markets are competitive. Therefore, we proceed to discuss policy and institutional issues related to the adoption of Bt cotton in West Africa.

The Model

Most *ex post* or *ex ante* analyses of the size and distribution of national economic benefits from adopting GM crops have been conducted with adaptations or versions of the economic surplus approach detailed by Alston and Pardey (1999). This approach is also termed a partial equilibrium displacement model because it considers only the effects of the technology change in the market where the technical change occurs. The model disregards the effects in other markets, such as input markets. We based the economic surplus model used in this study on a set of equations that depict the cotton market in West Africa from which a set of formulas are derived to estimate consumer, producer surplus and innovator surplus.

We augment the model with the inclusion of probability distributions that replace individual parameters. The idea behind this replacement is to perform a rigorous sensitivity analysis of model parameters and to introduce risk considerations into the model as described in Falck Zepeda *et al.* (2008). Then, we estimated annual producer, consumer and innovator surplus for the period of the simulation and for each scenario. In addition, we estimated the Net Present Value (NPV), and when appropriate, the Internal Rate of Return (IRR) for each year of the simulation and sum to a total value.

The countries of Benin, Burkina Faso, Mali, Senegal and Togo were included as standalone countries in the estimations. We group the rest of the cotton producing countries in West Africa and other regions under Rest of the World (ROW) category. In most cases, we used triangular distributions to reflect a distribution of outcomes. The triangular distribution is parsimonious at the minimum, most likely and maximum values, fully describe the distribution. Furthermore, the triangular distribution approximate the normal distribution over repeated sampling draws. The distribution is widely used in production economics and the finance literature for modeling risk. The values for the distribution of the model parameters where compiled from the literature (Hardaker et al. 2004).

We inputted the model into a spreadsheet and then ran Monte Carlo simulations using the programme @Risk™. The program calculates and saves output variables designated in advance by drawing quasi-randomly from the distributions included in the model. After the program estimates and saves output, the program repeats this process for a designated number of times by the user. The @Risk™ program saves results, and when all iterations are done, calculates statistics over all simulation results for the output variables. In this paper, output variables are producer, consumer, innovator, and total surplus, and net present value and internal rates of return.

The formulas for changes in domestic and ROW producer and consumer surpluses used in our study were:

$$\Delta \mathrm{CS} = \mathrm{P}_0\, \mathrm{C}_0\, \mathrm{Z}\, (1 + 0.5\, \mathrm{Z}\, \mathrm{h}_a),$$

$$\Delta \mathrm{PS} = \mathrm{P}_0\, \mathrm{Q}_0\, (\mathrm{K} - \mathrm{Z})\, (1 + 0.5\, \mathrm{Ze}_a),$$

$$\Delta \mathrm{IS} = \mathrm{A}_t\, (\mathrm{P}_{\mathrm{Bt}} - \mathrm{P}_{\mathrm{Conv}}) = \mathrm{At} * \mathrm{TF}_t$$

$$\Delta \mathrm{TS} = \mathrm{DCS} + \mathrm{DPS} + \mathrm{DIS} - \mathrm{DC}_{\mathrm{Dep}}$$

$$K = \left[\frac{(\Delta Y}{\varepsilon a} + \frac{\Delta C}{(1+\Delta Y)} - \frac{TF}{TC} \right] \times A \times R \times S$$

where ΔCS= Change in consumer surplus, ΔPS=Change in producer surplus, ΔIS=Change in innovator surplus, ΔTS= Change in Total surplus, P_0 is the price without the innovation, C_0= Quantity consumed without the innovation, Q_0= Quantity produced without innovation, K is the proportional size of the supply shift, Z = is the price change associated with the supply shift, P_{Bt} is the price of Bt cotton, P_{Conv} is the price of conventional varieties and C_{Dep} are the costs necessary to develop

Table 2a: Assumptions Used in the Estimation of Economic Surplus Model for the Adoption of Bt Cotton in West Africa

Assumptions	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Source(s) of assumptions
Maximum adoption rates (%)	0% in WA 20% ROW	30% in WA 20% ROW	60% in WA 20% ROW	50% in WA20% ROW	Fluctuating adoption in Benin and Mali, 30% in rest of WA,20% ROW	Based on Cabanilla,et al. 2005.
Total R&D & Biosafety lag (years)	0	6 Burkina Faso, 9 other WA countries	5	6 Burkina Faso, 9 other WA countries	6 Burkina Faso, 9 other WA countries	Own (subjective) assumption
Adoption lag (years)	0	5 Burkina Faso, and other WA countries	5	5 Burkina Faso, and other WA countries	5 Burkina Faso, and other WA countries	Own (subjective) Assumptions
Year at maximum adoption level	7	7	7	7	7	Own (subjective) Assumptions
Years to dis-adopt	0	5	5	5	5	Own (subjective) assumptions
Total years simulation	23	24	23	24	24	Sum of all components of adoption pattern

Notes: WA = West Africa, ROW=Rest of the World, Scenario 1=No adoption in West Africa, adoption in the rest of the world, Scenario 2 =WA adopts available private sector varieties, Scenario 3 =WA uses West African varieties backcrossed with private sector lines, Scenario 4 =WA uses West African varieties backcrossed with private sector lines plus a negotiated premium Scenario 5= WA uses West African varieties backcrossed with private sector lines with irregular adoption.

and deploy the technology including biosafety regulatory compliance costs, ΔY is the expected yield difference between Bt and conventional cotton, e_a is the elasticity of supply of cotton, ΔC is the cost difference between Bt and conventional cotton, TF is the technology fee, TC is the Total costs of production, A is the adoption rate, R is the probability of R&D success (assumed in this paper to be 100 per cent), and S is the share of the hectares planted to Bt cotton in each country.

Simulations were conducted over a set period, then output variables were calculated for each year and then the results were transformed to net present values. Note that the values for elasticities, yield and cost differences, prices and quantities, and other parameters are specific to the country and region groups, unless specified differently.

Modelling Scenarios

Scenario 1: No country in West Africa adopts Bt cotton, while cotton-producing countries in the ROW adopt at a constant rate of 20 per cent. Maximum adoption rates are achieved in the ROW in year seven. The total time simulated is 23 years. For the ROW countries, we assumed a triangular distribution with a minimum, most likely and maximum technology fee of US$15, US$ 32, and US$ 56 per hectare respectively. Note that these estimates from the literature are relatively high as they correspond to the technology fees charged for both developing and industrialized countries and thus the results of our simulations will tend to be conservative estimates.

Scenario 2: Adopting countries in West Africa use Bt cotton but after backcrossing to local varieties. This policy increases the lag time to deploy the technology. Thus, there is a delay in terms of producers receiving the stream of benefits. Lags are extended to adopting countries by three years. Adapted local varieties may yield more than foreign varieties, while ensuring a higher acceptance by farmers in the region (Qaim et al., 2006). Therefore we have modified yield parameters to reflect potential yield advantage from adapted varieties. This is the most likely scenario for the case of Burkina Faso and the rest of countries in West Africa.

Scenario 3: adoption starts in 2012 in Burkina Faso, followed by the other countries three years later. The maximum adoption ceiling in the region is 60 per cent. Adopting countries use adapted local varieties. We assume a public release; therefore, there is no technology fee. Many countries in Africa are considering of the involvement of the public sector in the development and distribution of Bt cotton technology.

Scenario 4: Literature reviews have shown the importance of the technology fee levels in determining the gains from the adoption introduction of Bt cotton. Lower technology fees tend to increase gains by producers by reducing input costs and by providing incentives to increased adoption. Taking into consideration the significant negotiating power of farmer unions and marketing associations have in West Africa, we explore the possibility that they are able to negotiate a lower technology transfer fee compared to the three previous scenarios. We reduced the technology fee for by 40 per cent across all parameters of the triangular distribution to gain a sense of the potential impacts of such policy. The minimum, mode and maximum technology are then set to 9, 19 and 34 dollars per hectare, respectively. We also increased adoption rates slightly to a maximum of 50 per cent because of the lower price of Bt cotton seed. Other assumptions remain the same as those used in Scenario 3.

Scenario 5: Taking into consideration the experience with the adoption of modern varieties in Africa, we allowed for a pattern of adoption, dis-adoption and re-adoption in Mali and Benin. The purpose of this scenario is to emphasize the importance of addressing institutional and governance considerations and the farmer vulnerability to fluctuations in seed availability and hence farm income. Thus, this scenario illustrates the impact of fluctuating adoption rates and institutional issues on the level and distribution of benefits as documented in other countries in Africa (Gouse et al. 2005). We therefore modify the smooth sigmoid adoption curve used in the previous four scenarios to describe and somewhat irregular adoption path. We assume that a drastic fall in world cotton prices, a political turmoil, or a drought event could affect cotton production in general, but there may be a larger (and perhaps faster) reduction could be expected in Bt cotton areas, given the higher seed costs. Except for the irregularity in adoption rates, all other assumptions in Scenario 5 are the same as those made in Scenario 3.

Discussion of the Parameters Considered

We present the parameters and the assumptions used in the model in Tables 2a and 2b, along with the literature consulted to obtain parameter values. We instructed the simulation programme to repeat the process 10,000 times for Scenarios 1-4 and 25,000 times for Scenario 5. A higher

Table 2.b: Assumptions for Probability Distributions used in the Estimation of Economic Surplus Model for the Adoption of Bt Cotton in West Africa. cont.

Assumptions	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Source(s) of assumptions
Technology fee (US$/ha)	Triangular (15, 32, 56) for ROW	Triangular (15, 32, 56) for WA and ROW	Public Sector release-no charge (15, 32, 56) Triangular for ROW	Triangular (9,19, 34) for WA and (15, 32, 56) for ROW	Triangular (15, 32, 56) for WA and ROW	Falck-Zepeda et al., 2000; Huang et al., 2003; Bennett et al., 2004; Huang et al., 2004
Supply eelasticity (Units)		Triangular (0.3,1,1.5)	Triangular (0.3,1,1.5)	Triangular (0.3,1,1.5)	Triangular (0.3,1,1.5)	Minot and Daniels 2005;Dercon 1993, Delgado and Minot 2000,Alston, Norton and Pardey, 1995
Yield advantage of Bt over conventional varieties (%)	Triangular (0, 0.2, 0.4) for ROW only	Triangular (0., 0.25, 0.45) for Burkina Faso and WA for ROW (0., 0.2, 0.4)	Triangular (0,0.2,0.4) for WA and ROW	Triangular (0,0.25,0.45) for Burkina Faso and WA for ROW (0., 0.2, 0.4)	Triangular (0,0.25,0.45) for Burkina Faso and WA 0., 0.2, 0.4) (for ROW	Falck-Zepeda et al., 2000; Huang et al., 2003; Bennett et al., 2004; Huang et al.,
Cost advantage of Bt over conventional varieties (%, net of technology fee)	Triangular (0, 0.06, 0.12) equivalent to a reduction of 0, 7, 14 applications for ROW only	Triangular (0, 0.06, 0.12) for ROW and (0, 0.13, 0.26) for WA equivalent to a reduction of 0, 7, 14 applications	Triangular (0, 0.06, 0.12) for ROW and (0, 0.13, 0.26) for WA equivalent to a reduction of 0, 7, 14 applications	Triangular (0, 0.06, 0.12) for ROW and (0, 0.13, 0.26) for WA equivalent to a reduction of 0, 7, 14 applications	Triangular (0, 0.06, 0.12) for ROW and (0, 0.13, 0.26) for WA equivalent to a reduction of 0, 7, 14 applications	Cabanilla et al. 2005; Bennett et al., 2004; Huang et al. 2004

Table 2.b continued

Table 2.b continued

Assumptions	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5 assumptions	Source(s) of
Adaptive R&D / Biosafety regulatory costs (US$ total)	0	$120,000 distributed over 4 years in BF, $90,000 distributed over 3 years rest adopting countries ion WA	$120,000 distributed over 4 years in BF, $90,000 distributed over 3 years rest adopting countries ion WA	$120,000 distributed over 4 years in BF, $90,000 distributed over 3 years rest adopting countries ion WA	$120,000 distributed over 4 years in BF, $90,000 distributed over 3 years rest adopting countries ion WA	Pray et al. 2005, Quemada 2003 and Falck Zepeda and Cohen, 2006

Note: The triangular probability distributions used in the simulations are fully described by minimum, mode and maximum values. In the table above values for these three parameters are included in parentheses in each cell of this table, when appropriate.

number of simulations in Scenario 5 were necessary as simulation results fluctuated significantly due to fluctuating adoption patterns in this scenario. We, therefore, wanted to ensure robust statistical summaries estimated for the aggregate results. A more in-depth description of the parameters is in Falck Zepeda, *et al.* (2008).

1) Time lags: time lags defined as the sum of the time required for adaptive research and development (R&D) and biosafety regulatory process in the innovating country.
2) Cost of compliance with of compliance with biosafety regulations and/or R&D: Since this is an ex-ante study, we used data from other developing countries including India and China (for example, Pray *et al.* 2005; Quemada 2003; Falck-Zepeda and Cohen 2006). When the cost of compliance with biosafety regulations is included, that benefit values to producers will most likely decrease.
3) Technology diffusion pattern: In the simulations, Burkina Faso took the leading role because this country has approved the commercial release of the Bt cotton. Other countries including Benin, Mali, Senegal and Togo, adopted after an evaluation period. The later assumption is controversial but reflects the experience of other regions of the world (i.e. the case of herbicide resistant soybeans in Brazil after approval in Argentina).
4) Model elasticities: Given the limited information concerning the supply elasticity of cotton in West Africa, the unitary elasticity was assumed as the most likely value. To set the range of the supply elasticity values, we consulted the literature. The final triangular distribution used took a minimum value of 0.5 and a maximum of 1.5, with a mode value of 1.0. We chose deliberately a more conservative minimum value ($\varepsilon = 0.3$) as seen in Table 2b.
5) Yield advantage: We drew values of the difference between Bt and conventional yields from existing literature. Note that the minimum value at 0 per cent allows for the possibility of no yield effect induced by the Bt trait. If there is no pest attack there is no reason to observe a yield difference between the Bt and conventional variety. The likelihood is that if there is still a difference this is unrelated to the trait but rather to the germplasm used.
6) Cost advantage: Refers to the per unit cost savings from reduced pesticide use resulting from the use of Bt varieties. As in the case of yield advantages, we consulted the published literature to obtain values for the triangular distribution that we use in our simulations. The minimum cost difference was set to zero since a Bt variety

does not necessarily reduce the need for insecticide applications. The experience in other countries has shown that even in the case of successful adoption of a Bt cotton technology and successful control of the primary pests, secondary pest populations can become economically significant and therefore may require pest applications. The cost of controlling secondary pests then could offset benefits from reduced applications of pesticides to control the target pest.

Notice that the simulations account for the possibility that farmers may be worse off by using the Bt cotton technology when there is no yield advantage and/or no costs advantage.

Results

Scenario results

Table 3 introduces results expressed in actual and present values. The overall result is that the change in economic surplus is positive with the adoption of a Bt cotton technology in West Africa. The results of the simulations show that producer surplus gains are qualitatively similar amongst all countries. On the other hand, the probability that consumers would gain with Bt adoption are very high. These overall results vary from one scenario to another. One of the benefits from using a stochastic simulation model is the ability to compare and analyze variability at different levels of analysis. We observed significant variability at the country level masked within the average simulation results.

Table 3 introduces average benefits for consumers, producers and innovators for the more realistic scenarios 2, 3, 4 and 5. It is also important to point out that in Scenario 3 there is no innovation surplus since there is no technology fee. In the case that West Africa would choose not to allow cultivation of Bt cotton (Scenario 1/Baseline), the results show that producers would unequivocally loose from this policy. These losses are a consequence of price reductions driven by supply shifts from technology adoption in the rest of the world. Price reductions do induce a gain by consumers; however, consumer gains do not match producer losses. Therefore, not adopting Bt technology would generate net losses for the region.

Comparing Scenarios 2 and 4, we see that both lowering technology fees and higher levels of technology adoption may improve the level of benefits but also its distribution. In almost all countries,

Table 3: Level and Distribution of the Present and Actual Value of Economic Surplus in West Africa and Burkina Faso, by Scenario (Millions US$)

Actors	Present Values					Actual Values				
	S 1	S 2	S 3	S 4	S 5	S 1	S 2	S 3	S 4	S 5
West Africa										
Producers	-28.1	32.9	30.6	33.6	20	-77.6	199.7	201.5	208.3	145.9
Consumers	0.5	0.6	0.7	0.6	0.5	1.4	1.56	1.9	1.7	1.5
Innovators	0	48.	0	28.8	37	0	219.3	0	131.5	188.7
Total Surplus	-27.7	81.1	31.0	62.8	58	-76.2	420.1	203.1	341.1	335.7
Burkina Faso										
Producers	-7.0	13.4	12.9	13.8	13.5	-19.3	56.7	53.5	58.6	51.2
Consumers	0.1	0.1	0.2	0.1	0.1	0.4	0.4	0.5	0.4	0.4
Innovators	0	14.7	0	8.9	14.7	0	54.9	0	32.9	54.9
Total Surplus	-6.9	28.3	13.0	22.7	28.3	-19.0	111.9	56.4	91.9	106.5

Note: 1) Source: Falck Zepeda et al. (2008), 2) The values for producer, consumer and innovator surplus do not add to the value for total surplus shown in the table because the values presented in each cell of this table are the average of the thousands of iterations undertaken in each scenario.

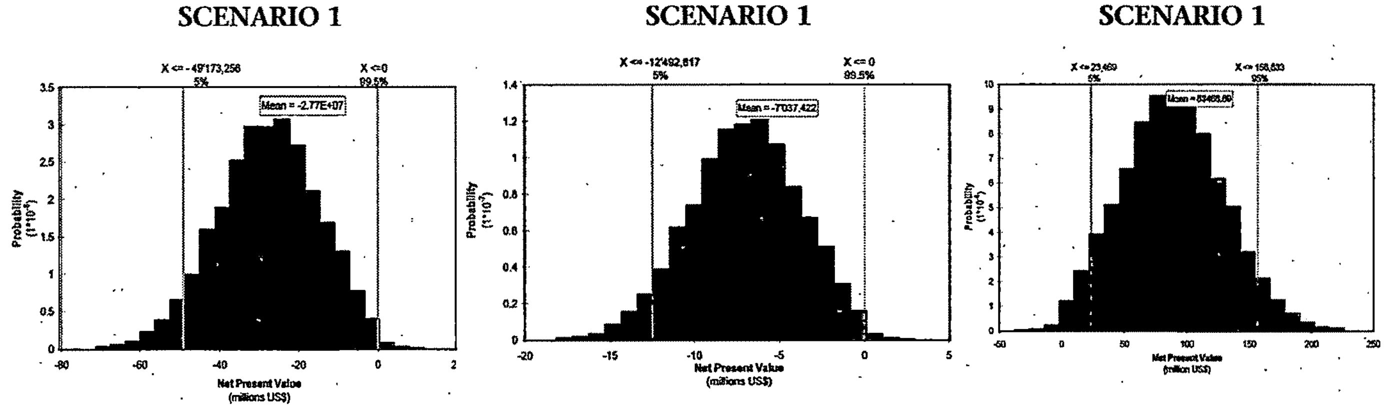
producers and consumers are better off with a reduction in technology fees as in Scenario 4. Certainly, innovators are worse off. Therefore the question of minimal technology fees to enter a market become relevant. Alternatively, the question could be framed as what is the minimal technology fee per area that induces a developer to invest in a market, as this will have an impact on profitability. Similar questions can be raised with regard to the public sector. One of the public policy considerations is whether developers -and innovation- will be affected by price reductions and how. In Table 4, we can also see the impact of not addressing institutional issues that may disrupt adoption processes. In Scenario 5, irregular adoption processes affect significantly producers in Benin and Mali, but they are not the only stakeholder affected as innovators are also affected.[3]

Figures 1 a-c introduces the distribution of net present values for the baseline scenario 1. The probability that West Africa in general and Burkina Faso a loose from not adopting Bt cotton is very high (99.5% certainty) as shown in Figures 1a and 1b. Similar results occur in other countries. As expected, with a price decrease, consumers gain from the use of Bt cotton. Senegal uses a large proportion of the cotton domestically produced, and therefore the change in consumer surplus due to the adoption of Bt cotton would most likely be high (Figure 1c). The probability of a negative change in consumer surplus is very low. The probability of having a negative change in total economic surplus is much lower in Scenario 2 (4 per cent) than in the baseline scenario (99.5 per cent).

The introduction of local adapted varieties makes a big difference in our modeling efforts. The core idea for this scenario is to examine the trade-off between using a variety available now versus a using a variety produced sometime in the future. This tradeoff needs to be compared to the additional cost involved with adaptive R&D necessary to introduce the Bt gene into local varieties. Results show that the use of a local variety with higher yield may compensate for the time and cost to develop the technology in the first place.

In scenario 4 in Table 3, benefit level increases for both consumers and producers in West Africa, with a concurrent reduction in innovator surplus. Consumer gain through output price decreases while producers increase their own gains from a reduction in input costs. Lowering the technology fee charge does benefit producers and consumers. The real questions are how much a reduction and what is the mechanism by

Figure 1. Distribution of Present Value of Total Surplus for Scenario 1



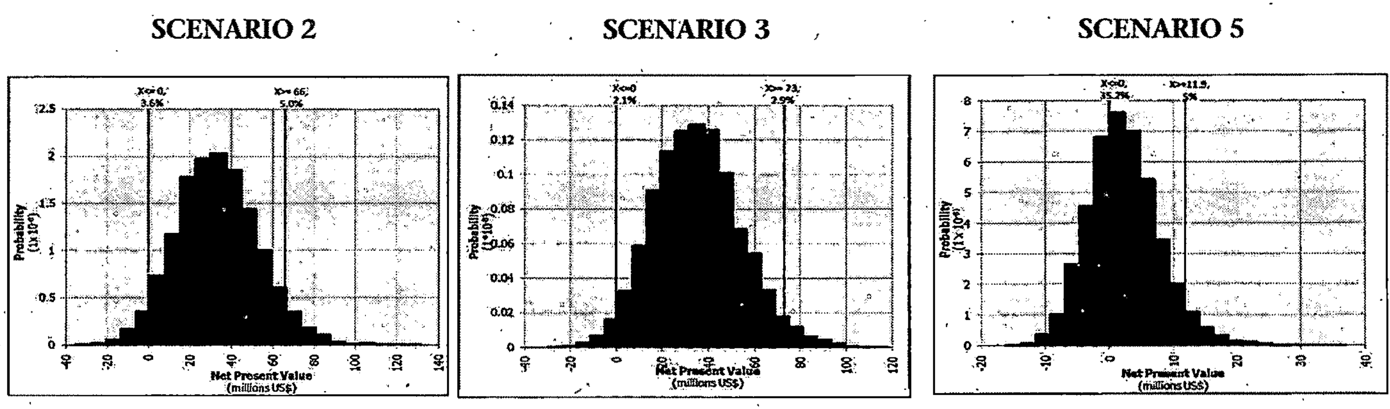
a. West Africa - Total surplus

b. Burkina Faso - Producer surplus

c. Senegal - Consumer surplus

Source: Falck Zepeda, et al. 2008.

Figure 2. Distribution of Total Surplus Across Scenarios



a. West Africa total surplus

b. West Africa total surplus

c. Benin producer surplus

which farmers can negotiate price reductions in the region. Furthermore, reducing prices tends to decrease variability and downside risk. These results are indeed a reflection of a reduced financial risk in the cotton sector derived from driving input prices down, to get them a close to a competitive market price as possible. However, decision makers have to be conscious that there is a threshold under which developers will not deliver a product to a particular market as it becomes un-economical. The case of public sector product delivery free (or close to free) requires much more attention.

When we consider introduction of irregular adoption rates in countries such as Benin and Mali, as in Scenario 5, there is significant effect on outcomes. In both countries, irregular adoption rates reduce producer and total surplus compared to previous scenarios (Tables 3 and 4). This is not the only impact, as there is a concurrent increase in the level of downside risk. In comparison to Scenario 4, we observe a decrease in consumer surplus and increased innovator surplus. The probability distributions for the chance in producer surplus reveal that disrupted adoption causes a higher probability of negative producer surplus (Figures 2a and 2b). The probability of negative change in producer surplus can be as high as 35 per cent in Benin (Figure 2c). The country with lowest probability of a negative outcome is Senegal, with a still sizable 20 per cent probability. Interesting to note that consumer surplus is not affected much by irregular adoption as adoption in the ROW dampens potential losses from using the technology in West Africa.

The change in total surplus and consumer and producer surplus do not vary much between Scenarios 2, 3 and 4 (Table 4). Neither, the distribution of outcomes varies much among these scenarios (Figures 2a, 2b and 2c). The probability distribution of change in total economic surplus for West Africa under Scenario 3 (Figure 2b) corroborates this statement. In this case, a very small reduction in the probability of obtaining negative outcomes within total economic surplus is observed in Scenario 3 (2.6 per cent) with respect to Scenario 2 (3.86 per cent). An example at the country level, in Burkina Faso, the probability of a negative change in total economic surplus is reduced from 5.8 per cent in Scenario 2 to 4.1per cent in Scenario 3. Similar reductions are observed for total, producer and consumer surplus in all countries in the region.

Policy and Institutional Issues

A review of the impact of Bt cotton in the developing world has shown that the technology can have a positive impact in small-scale farmers (see Smale *et al.* 2008), but that "much attention needs to be focused on the development of local institutions" (Tripp, forthcoming). Furthermore, the economic literature on the adoption of GM cotton has underlined the importance of taking into account the institutions in analyzing the success of these technologies, particularly within the context of small-scale agriculture.

The initial success of Bt cotton adoption in South Africa, for example, was derailed by the weakness in the institutional framework under it was initially developed, approved and commercialized (Gouse 2005). In China, the higher yields observed with Bt cotton was not matched with the expected reduction in insecticides, given the lack of information of proper management in hands of farmers (Pemsl 2005) and the lack of transparency in seed markets. These cases, as well as others, pinpoint how critical is it to address and understand the institutional framework - including formal and informal institutions - and to assess the possible institutional barriers to the successful deployment of Bt cotton or any other GM technology.

A common conclusion of many GM studies is stating the need of having in place effective biosafety regulations and increased investment in biotechnology as key factors in the successful commercialization of GM crops (Smale et al. 2008). A recent study of Bt Cotton by Tripp (forthcoming) concurs with this assessment but shows that "broader institutional issues ... need to be addressed if biotechnology is going to have an impact in most developing countries." From the experience of other developing countries that have already adopted Bt cotton, several lessons can be learned by implementing groups in West Africa.

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Innovation system: Countries face alternative options to ensure farmers have access to appropriate technology. Options include using technology developed by multinational companies, or by the international research system, or alternatively to develop the technology by themselves. The appropriate choice will depend on the development of the country's own innovation system and the level of financial and human resources, available to address the creation or adaption of appropriate technologies. In all cases, the need exist to have a functional system to characterize, conserve and improve genetic resources for agriculture, as they are the backbone of all crop and animal improvement systems.

Local adaptation of cotton varieties: Some countries such as Mexico, Colombia, and South Africa used foreign Bt varieties directly

Table 4: Average Present Values of Economic Benefits to the Cotton Sector, by Sector Actor and Country (Values in US$)

Country	Producer surplus	Innovator surplus	Consumer surplus	Total surplus without innovator	Total surplus
		SCENARIO 2			
Benin	7,397,656	11,381,600	203,629	18,931,930	7,550,328
BF	13,452,700	14,778,650	139,729	28,303,260	13,524,610
Mali	8,416,729	15,339,090	102,146	23,811,640	8,472,551
Senegal	553,824	1,305,254	91,535	1,904,289	599,035
Togo	3,045,468	5,172,745	20,321	8,192,210	3,019,465
ROW	4,073,093,000	2,794,727,000	1,477,385,000	8,345,204,000	5,550,478,000
		SCENARIO 3			
Benin	6,839,931	-	250,147	7,039,122	7,039,122
BF	12,850,065	-	171,652	12,953,894	12,953,894
Mali	7,404,722	-	125,483	7,483,881	7,483,881
Senegal	494,871	-	112,447	560,993	560,993
Togo	2,988,217	-	24,964	2,966,857	2,966,857
ROW	4,536,370,920	2,794,726,929	1,813,242,661	9,144,340,511	6,349,613,581

Table 4 continued

Table 4 continued

Country	Producer surplus	Innovator surplus	Consumer surplus	Total surplus without innovator	Total surplus
			SCENARIO 4		
Benin	7,579,815	6,828,961	223,300	14,581,120	7,752,158
BF	13,789,120	8,867,198	153,230	22,747,890	13,880,690
Mali	8,525,793	9,203,451	112,017	17,794,940	8,591,486
Senegal	560,684	783,151	100,379	1,397,890	614,739
Togo	3,167,267	3,103,650	22,284	6,246,877	3,143,227
ROW	4,441,543,000	2,794,728,000	1,619,545,000	8,855,815,000	6,061,088,000
			SCENARIO 5		
Benin	2,307,335	7,415,446	202,151	9,873,975	2,458,529
BF	13,499,500	14,778,660	138,715	28,349,060	13,570,390
Mali	848,027	9,085,328	101,405	9,988,436	903,108
Senegal	557,971	1,305,253	90,870	1,907,769	602,517
Togo	3,065,317	5,172,746	20,174	8,211,913	3,039,167
ROW	4,078,755,000	2,794,726,000	1,465,509,000	8,338,990,000	5,544,264,000

Note: 1) Scenario 1 is not presented here due to space constraints, 2) The values for producers, consumers and innovators surplus do not add to the value for total surplus and total surplus without innovator shown in the table. Values for all the components of surplus presented in each cell of this table are the average of the thousands of iterations undertaken in each scenario.

in the first stages of the adoption process. The policy of allowing foreign varieties may not be feasible in West Africa as many countries have strict regulations regarding the use of planting of varieties. If adaptation of the trait (Bt gene) into local varieties is viewed as a necessary process, additional time and funding will be required.

Institutional limitations: Successful diffusion of GM cotton in developing countries depends very much on strong public institutions, including the clear support of the government, a dynamic research sector, and the availability of credit for funding investments in agricultural inputs. An area of particular importance is the information that farmers need to have for the adequate management of a GM crop and the flow of information to and from producers regarding the technology and its place in society.

Despite the adoption of Bt cotton, many adopting countries (i.e. China, India, Colombia and others) are still overusing insecticides, mainly due to the lack of proper information regarding the management of the technology. In other countries, pesticides are barely applied or are applied using the wrong dosage for controlling insects. The later may be the case in West Africa as there is a history of low chemical use by farmers (Horna *et al.* 2008). Therefore, there is the need to establish an efficient and enabling knowledge sharing mechanism to ensure that farmers get the right information at the right moment. This is, of course, connected to the idea of developing trust in the sources of information and the knowledge networks that operate in many countries.

Legal Frameworks including Biosafety and IP

a) Biosafety

A regulatory process is needed for GM cotton varieties to be officially release in most countries. The biosafety regulatory process involves a risk assessment steps. Several actors and stakeholders including regulators, decision makers, users, and developers interact to define, assess and decide the outcome. Actors involved in this process may contribute to ensure biosafety assessment, testing, and the development of genetically modified crops; and provide support in training, capacity building, regulatory strategies and policy development. In most countries, one of the first steps for the approval of GM varieties is the implementation on confined field trials (CFTs). CFTs provide the technology developer and decision makers with the opportunity to evaluate the performance of GM plants. The CFTs allow collecting data required for the biosafety assessment, as well as, variety testing, registration, and seed certification purposes. The regulatory agency will supervise the implementation of the CFTs after the application form has been approved, as well as analyze data submitted by the proponent, and determine the appropriate course of action after commercial release stage has been approved.

One of the potential post release strategies, in the case of cotton, is the establishment of an insect resistant management strategy including the creation of a refugia. Hence, one critical issue is to evaluate, and recommend, if needed, insect resistance management practices along with the introduction of Bt cotton variety. Bt expression introduces selective pressures on a pest population. Eventually, individual pests that are resistant to the Bt protein will survive and thrive, rendering the technology obsolete. Scientists devised various strategies to lengthen the time until resistance occurs. One successful strategy to date has been setting aside areas planted with non Bt cotton varieties where resistant individuals mate with non-resistant individuals, thus diluting the proportion of resistant individuals. The set aside is called a "refugia".

There are different variations in terms of whether farmers are allowed to spray for non-target insects in the refugia and the relative area dedicated to the set aside. As indicated before, the refugia have been successful so far in delaying the appearance of resistance to the Bt gene under field conditions. Bt cotton was introduced back in 1996 in the United States and so far, no case of resistance has been observed, mainly due to the effective management of the refugia. Nevertheless, refugia requirements for GM crops are much more difficult to comply in areas characterized by smallholdings, which is the case of most cotton farmers in developing country. Not only farmers have to understand the importance of the refugia strategies but also there must be effective mechanisms to regulate its compliance. The roles that the private sector - including ginneries - and the public sectors will play have to be clearly defined and financed. The case in China merits some careful consideration as the refugia in this country has not been deemed necessary due to the farming system in place that seems to act as alternative refugia.

If target pests are present at high densities or populations persist for an extended period, the need may exist for supplemental insecticide applications to prevent further yield losses. Furthermore, even when there is adequate control of the target pests, secondary pests that used to be controlled – albeit indirectly – when controlling the target pest may become economically significant. Secondary pest evolution is a well-known issue in breeding and managing plant genetic resistance, which needs to be addressed as early as possible through variety release plans and regulatory approval processes. Integrated Pest Management (IPM) practices, scouting techniques, and agronomic management practices must keep pace with a changing pest population.

Another critical issue is the possibility of incidental gene transfer to wild cotton populations. Although this possibility is remote, some countries have chosen to limit the areas where Bt cotton is planted. In the US, Bt cotton varieties are not permitted for cultivation in the Southern part of Florida, Hawaii, U.S. Virgin Islands or Puerto Rico. In Mexico, Bt cotton varieties are not permitted for cultivation in the southern states, as there are wild relatives of cotton in the region. Interestingly enough, the possibility that modern cotton varieties may be able to cross sexually with wild relatives is very low.

b) Intellectual property right

In many countries in West Africa, governments and state owned enterprises freely distribute seed to farmers. Many questions arise from this approach. For example, how will IP issues affect innovation and science and technology in West Africa? Will the public sector attempt to recuperate some of the investments made in adaptive research? How is the technology fee for using the Bt technology going to be recuperated? Are there institutions to guarantee that the seed won't be multiplied illegally?

The later situation has indeed occurred in other countries who have used Bt cotton in the past including India and China. The other issue is stewardship and liability. Even in the case where private sector "donates" the technology free for use by producers, the national and international regulatory regime has not evolved sufficiently to create a regime that would address the issues of liability. Furthermore, the need exists to provide incentives to stakeholders, to ensure product stewardship along the production chain. Certainly, the donor, which may be a private sector organization, has the interest of protecting its technology for misuse. In essence, the mechanisms to alleviate the need to manage liability and to ensure product stewardship need to be in place to ensure proper technology deployment.

Cotton sector organization and coordination: In West Africa, the cotton sector has been evolving over time. Actors, vertical and horizontal coordination and commercialization channels have evolved responding to internal and external realities of cotton production, especially subsidies by industrialized and some developing countries to their own cotton production systems.

For example, Benin has reduced the role of the quasi-state enterprise SONAPRA and has introduced competition in the distribution of inputs and marketing of cotton but the government is still subsidizing the farmers (Minot and Daniels, 2004). Mali has privatized the state owned cotton seed company HUICOMA, and has created a new price setting mechanism that ties producer prices to world market prices but the CMTD (85 per cent owned by the government) controls most of the production, ginning and marketing of cotton (Basset, 2006).

One the one hand, the vertical institutional coordination mechanism in place in West Africa can ensure deployment of the Bt cotton technology in the region. On the other hand, this same coordination mechanism may introduce inefficiencies due to lack of competition and may in turn derail the proper introduction of the technology. The need exists for the state owned enterprises to evaluate the marketing channels and to provide the proper technology transfer support to ensure the proper deployment of the Bt cotton technology in the region.

Alternative production methods: Alternative production methods, including organic cotton production, have been growing at a fast pace in many parts of West Africa and other developing countries, but remain a small proportion of total area planted (Falck Zepeda 2006). If farmers consider this alternative production sector important, especially for its foreign market potential, planting GM crops could pose a risk for their viability. Ginneries and exporters could lose their certification, as the main market for organic cotton is Europe. In most cases, certification for these markets requires zero percent use of GM seed. If this is the case, there is need to examine closely the benefits, costs, and risks of managing a co-existence system. In addition, the need exists to explore the different mechanisms to guarantee segregation, labelling and traceability, which can be expensive for implementation.

Landlocked economies: Some countries in West Africa are landlocked. Their exports must pass through neighbouring countries to reach export ports. Ratifying parties to the Cartagena Protocol on Biosafety have to comply with article 19(1) "each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.".

Such a measure would compel any Protocol member to likely include advanced inform consent and the possibility to label each shipment with a detail on the nature of the GM events included in the shipment. If a country, especially those ratifying parties to the Protocol, introduces one or more types of GM cotton in the future, it may have to test each shipment of cottonseed to make sure the labelling is correct or alternatively develop segregation, traceability and identity preservation systems to ensure the transboundary movement of GM materials. The cost of such procedures would be significant, even if it the shipment is only destined for a neighboring member country that has approved the same GM cotton event when passing through country that has not approved the GM cotton event. The issue of asynchronous approvals needs to be addressed urgently in West Africa and thus the need exists to explore regional approaches to biosafety and biotechnology assessment and decision-making.

Concluding Remarks

Policy makers in West Africa have a difficult task in front of them. On the one hand, decision makers need to screen and assess competing claims on the benefits, costs and risks of these genetically modified technologies and decide on their role in terms of improving producer productivity, increasing their resiliency and creating prosperity; on the other hand, they have to promote agricultural productivity while protecting the environment and biodiversity. The overarching goal of this paper is to contribute to the empowerment of decision makers in West Africa by discussing results of economic simulations but also discussing the potential institutional issues related to the adoption of Bt cotton in West Africa. The discussion in this paper can help support decision makers understand policy options and their trade-offs, while empowering them to choose strategies for the cotton sector in their countries.

Results from our simulations and from other papers in the literature indicate that West African governments need to ensure long-term productivity gains to match international levels and to compete with subsidies and other government support programmes in place in other cotton producing countries. These results show that West Africa is worse off when facing other countries adopting productivity enhancing technologies such as Bt cotton. West African countries will need to adopt productivity enhancing technologies to compete in global markets.

Several factors shape the level and distribution of net benefits derived from the potential adoption of Bt cotton in West Africa. A major factor is seed prices that include the technology premium. The technology fee has to balance the value of the pest damage relative to other constraints, as well as the potential pest control alternatives and producers' ability and willingness to pay. The amount charged for this technology fee will be critical in the successful deployment of the technology in the region.

Burkina Faso has taken the first step in the region with the approval of Bt cotton commercialization. This fact determined the leadership role in terms of first adopter in our simulations. Burkina Faso is posed to capture a larger share of benefits from this technology. This fact contrasts with the relative low gains across all producing countries in West Africa from the adoption of the technology. As introduced in the discussion, we have used advanced risk simulation methods, plausible assumptions and have considered both negative and positive outcomes. We may think of our results as the most likely outcome from negative and positive outcomes in our simulations. In absolute numbers, the largest cotton consumption occurs in Senegal. However, our simulations indicate that Benin is the country where consumers could potentially gain from Bt cotton adoption in the region, as they have the highest consumption of locally produced cotton.

Published studies on the impact of Bt cotton in other countries indicate that a larger share of benefits accrue to adopting producers. These findings do not hold in our simulations. The innovator captures the largest shares of benefits compared to the actors in the cotton sector. These results directly relate to the conservative assumptions used in our simulations. Thus, they may be thought as the lower bound estimates of gains from the adoption of Bt cotton in West Africa. At the same times, these results are a call for West African countries to focus on the proper deployment strategies and to anticipate issues related their deployment, in order to minimize and/or mitigate these issues before they become binding constraints.

Our discussion on the policy and institutional factors serve to emphasize the role that these issues have in relation to technology adoption. Policy makers need to address all these factors to ensure the deployment of proper technologies to maximize societal gains arising from technology adoption. Scenario 5 (irregular adoption patterns) powerfully highlight the need to address institutional constraints and thus address irregular adoption pattern issues such as benefits increasingly accruing to innovators. This fact has serious implications for the practice of socio-economic impact assessments particularly those done *ex ante*.

Practitioners need to understand, in-depth, the institutional and policy context in which agricultural biotechnologies are being deployed by developers. These factors need to be included into estimations and simulations in order to ensure proper assessments. There needs to be significant advances in terms of identifying methods to model robustly these developments. Our initial simulations for the case of Bt cotton in West Africa show the need for modelling policy and institutions clearly.

Can producers in West Africa gain from the adoption of Bt cotton? Even when taking into consideration all the limitations and caveats from our study, producer can gain from having at least one more technology choice to choose from such as Bt cotton. This technology can help resolve one specific productivity constraint and thus contribute to the overall goal of poverty alleviation in the region. Proper deployment of the Bt cotton technology will need to be situated within the scope of overall economic development. A prudent course of action will evaluate options and give Bt cotton a proper role in the global economic development process. In essence, two distinct recommendations arise from our study. First, governments in West Africa need to identify and promote appropriate incentives to choose the best from technology alternatives and, second, the need exists to identify and mitigate policy and institutional constraints that may limit the proper technology deployment in West Africa.

Endnotes

[1] For a in depth description of scenario results and findings see Falck Zepeda, Horna and Smale (2008)

[2] The order Lepidoptera is the second most prevalent species order in the class Insect, including butterflies, moths and skippers. Members of the order are referred to as lepidopterans.

[3] We also conducted a regression analysis using @RiskTM in order to examine the sensitivity of our results to the assumptions underlying the structural model. Results are similar for producer surplus for all countries in West Africa. The levels of expected producer surplus are most heavily influenced by yield performance in

ROW and by price elasticities, followed by yield performance in each country, cost and other parameters of the structural model. In addition, we performed and advanced sensitivity analysis of the simulation results. We allowed positive and negative changes of 10 per cent steps in key parameters and performed repeated simulations with these values. In general, the advanced sensitivity analysis showed that our results are robust to changes in distribution parameters.

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Indian Efforts for Developing Biotechnology

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Abstract: Indian government shall remain in the forefront of developing a sound biotech base. A strong industry shall emerge in conventional biotech products. The local consumption shall also substantially rise. The patent expired products shall be the mainstay of modern product-portfolios. There would be more exploitation of GM-plants and the commercial introduction process shall be hastened. Large quantities of enzymes produced from GM organisms shall be in the market. Sizable sum has been spent in the public institutions. The industry is setting up robust facilities. More money shall therefore be channeled for applications, for which the basic research has to move up. Policy reorientation towards basic research in all areas of Indian needs shall benefit the country.

Key words: Biotechnology, health care, agriculture, recombinant therapeutics, Bt-cotton, Indian, biotech industry, manpower, biotech parks, GMOs

Introduction

Biotechnology is a set of techniques developed through basic and applied research, using biological materials or their analogues. The techniques are applied to organisms or their parts to produce, identify or design substances or to modify organisms. The applications are to meet human needs.[1, 2]

Indian Government Efforts

Indian government is in the forefront of developing a sound biotech base in the country. This situation emerges out of compulsions and social commitments to minimize foreign dependence, especially in the high-tech areas.

Indian foresight at the government level to benefit from modern biotechnology was much focused. It dates back to 1982, when a small

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division was created in the Department of Science and Technology of the Central Ministry of Science and Technology. Later on, in February 1986 a full-fledged Department of Biotechnology (DBT) was created[3] that was independent and , which could independently pilot singularly the multifaceted development in biotechnology in the country. Besides DBT, several other government departments also allocated funds for the development of biotechnology in the country.

The annual allocations[4] of funds over a decade during 1990-91 and 2000-01 (Table 1) by different departments are summarized below:

Table 1: Allocation of Funds by Different Funding Agencies for Promoting Biotechnology in India

Unit: million Rupees

Funding Agencies	1990/91		2000/01		% Growth over 10 years	
	Total	Biotech	Total	Biotech	Total	Biotech
DBT	655	655	1391	1391	212	212
CSIR	2351	24	9120	182	388	758
DST	2589	26	7798	234	301	900
DSIR	131	1	584	6	446	600
ICAR	3236	3	13990	280	432	9333
ICMR	396	15	1470	15	371	100
UGC	3495	35	14070	704	403	2011
TOTAL	**12853**	**759**	**48423**	**2812**		

While DBT remained the main department from the government to promote biotechnology, with the passage of time several other scientific departments also started taking more interest in developing this area. However, the quantum of money allocated by major departments like ICAR for agricultural research in biotechnology, ICMR for medical research in biotechnology and other departments like the Ministry of Human Resource Development, University Grants Commission (UGC), and All India Council for Technical Education (AICTE) for engineering research in biotechnology had been lower. Up to the present time, this trend continues and DBT remains the main funding organ of biotechnology development in the country. The combined expenditure in biotechnology from all the funding agencies of the government up to the end of 2006 is considered to be around Rs. 28000 million (US $650 million). While the efforts made thus far are praise worthy, time has come to allocate more funds, especially to promote innovative application; novel biotech applications based on local technology are not yet adequate. To enable this to happen, basic understanding in new biology has to be more profound. Concomitantly, basic science has to be put to fast applications.

Indian Commitments to Globalization in All Aspects of Biotechnology

India is a signatory to the World Trade Organization (WTO) and the country has enacted the provision of WTO in letters and spirit. The industrial licensing policy has been liberalized. Import duties have been rationalized. An equal label playing ground has been created for all the entrepreneurs, irrespective of whether they are Indian or foreigners. All steps have been taken in manners that do not create an imbalance in the core competence of the country. The Indian Intellectual Property Rights (IPR) laws have also been modified which are consistent with the Trade Related Intellectual Property Rights (TRIPS) of WTO. TRIPS require the member countries to comply with other aspects of IPR; these include protection of plant varieties, protection of trademarks and geographical indications. These have bearings in biotechnology. Indian Plant Variety Protection Act, enacted to comply with the provisions of TRIPS of WTO allows farmers to grow and retain the purchased and cultivated planting materials including seeds under farmers' rights. This process enables the use of F2 hybrids and varieties for cultivation, which assists and augments the needs of poor farmers for planting materials. In practice, this process has contributed to increased agricultural output from poor farmers, who were used to cultivate saved seeds of lower productivity.

Being also a signatory to the Convention on Biological Diversity (CBD), India is committed to protect its genetic biodiversity; concurrently it would have to consent to enabling access to people or parties to its genetic biodiversity. India has enacted its Biodiversity Law and has constituted its designated authority for accessing Indian Genetic Biodiversity by the CBD member countries.

India is making rapid progress after the initiation of liberalization in 1991.The decision to liberalize was not linked with political uncertainties that prevailed over the years, which continue to exist. The fast progress is linked with enhancement of productive abilities to manufacture and to export in various countries, especially in USA. Biotechnology shall make rapid progress as the abilities to export also enhances.

Indian Regulations for Genetically Modified Organisms and Substances[5]

Use of all genetically modified (GM) substances is regulated under the Environment (Protection) Act 1986 (EPA) and the Rules 1989 (Rules). Guidelines have been issued from time to time (1990, 1994, 1998, 1999 and 2008) to ease the application process. The genetically modified organisms (GMOs) can be living as in the case of microorganisms, plants and animals (GM edible yeast or lactobacillus or a host of agricultural produces such GM corn, potato, tomato, soybean, wheat, rice, mustard/ rape seed, etc); they can also be substances derived from GMOs that are non-living like inactivated GMOs, or substances derived from GMOs like proteins, nucleic acids, carbohydrates, lipids etc., which are produced from GMOs. The Rules require that all GM organisms and products thereof be introduced only after they are found to be safe; safe to the natural environment as well as safe for the health of human and animals. The law is based on precautionary principle.

India is a signatory to the Treaty on Cartagena Protocol, which is a Treaty for regulating the trans-boundary movement of GMOs; GMOs are designated as Living Modified Organisms (LMOs) in the Protocol. The Protocol is consistent with the Indian Rules on GMOs; Indian Rules also cover the products produced from GMOs and is thus wider in its scope.

The Department of Biotechnology (DBT) of the Government of India is considering setting up of a National Biotechnology Regulatory Authority (NBRA) as an independent, autonomous and professionally-led body to provide a single window mechanism for bio-safety clearance of genetically modified products and processes. The clearance process may become more versatile as the NBRA gets enacted and becomes operational. The creation of NBRA shall include defining its linkage with EPA and Rules, besides defined administrative authority.

While a rational regulatory structure is in place, there is an urgent need to invest for creating more competence for testing and assessing the safety of GMOs in public funded institutions. Public-private partnership overseen by the government could be other alternative structures. GMOs shall be utilized in several fields of human needs from drugs to food and drinks to agriculture (including animal husbandry, poultry, fisheries and aquatic life), industry-applications and environment management. But capacity to assess GMO technology in several facets such as risk assessment, risk management, unique identification and quantification when in the open environment especially in situations of advantageous presence, and long term impact of GMOs on human health and environment are areas where there are inadequacies. The areas of public education, public participation and public confidence building are also weak, which need strengthening. The existing infrastructure for handling GMOs need also be strengthened. Inadequate national capacity and skills to handle this technology would promote implementation of restrictive policies, which would be counter-productive to national benefits. Government efforts are to be strongly coupled with public and private organizations to handle such a highly science-based technology. Considering the potential benefits from GMO technologies especially in agriculture, the need for a priority to enhancing capacity building cannot be belittled.

Humankind has been exposed to GMOs for more than one decade. The horizon of knowledge has expanded. The perception of risks from certain GMOs has changed. The GM organisms used in contained environment for producing bioactive pharmaceutical substances have benefited millions; there is no report about adversities created by such organisms. In agriculture, GM crops have been produced more economically; they have benefited people. There is yet no proven report of irreversible damage to environment or human. Use of GM organisms has significantly contributed to production of certain biological substances like the enzymes, which have contributed to the emergence of better detergents, textiles, leather, poultry feed, etc. Indian biotechnology can make strong contributions in the international market in generic therapeutic biomedicines; at home, in agriculture the use of GMOs can contribute to significant gains in efficiency and productivity. In other areas like innovative diagnostic devices and pollution remediation, the GMO technology can perform more efficiently. India does not have major innovation round the corner. Therefore, available technologies should be used to the maximum extent to benefit the country; the regulations should not hinder the fast use of genetically modified substances in commerce, where products have proven safe elsewhere over a period of time. The Bt-cotton technology was approved in early 2002; there is yet no new GM plant approved for Indian agriculture. Is there is a need to introspect how the commercial introduction in India of elsewhere found safe GMOs can be made faster?"

Several new materials are evolving in the biotech horizon. Humanized monoclonal antibodies; si-RNAs; therapeutic human proteins made in plants or animals or viruses; modified cells; stem cells; and the like would use recombinant DNA technology at some stages of their manufacture and application. Many other substances would be designed, based on knowledge of cell biology and cellular regulations. The existing law does not clearly define if these substances are covered in all situations of their use. In their use, there are potential risks to the recipients. Should their safety be evaluated under the laws, regulating GMOs?

Biotechnology Parks: Government Efforts[6]

The government of India through the department of biotechnology has been instrumental to promoting the setting up of small and medium industries in biotechnology in different parts of the country. Towards these efforts the government with the assistance of the state governments has earmarked land and such zones have been designated as Biotechnology Parks. Such parks have been planned to provide financial and other logistical support to the young entrepreneurs who are not in a position to incur high capital expenditure in the biotech industry but have the intellectual capabilities to develop, design and perfect new biotech products and processes by utilizing such facilities.

Up to the present time, Biotech Parks have been created or planned/proposed in a number of states in India including Tamilnadu, Andhra Pradesh, Kerala, Karnataka, Uttar Pradesh, Punjab, Maharashtra, Gujarat, Uttaranchal, Rajasthan, Delhi, Orissa, Madhya Pradesh etc. The total investment contemplated in such facilities is estimated at approximately 15 billion rupees.

Biotech Parks are facilities created mainly to promote tiny, small and medium biotech entrepreneurs. Such entrepreneurs may find the parks attractive. Tiny and small entrepreneurs can initiate modern biotech products if they come from academia with proof of concepts with them. Such possessions require a backup of basic research with potentials of applications. The Indian academia is not biased upon the application-oriented research; there may not be many who are ready to come forward to take a business risk. Development of conventional biotech industries in the parks would tantamount to providing subsidized facilities. Can such industries pay back? Is there a need to review how the parks could promote modern biotech industries in preference to the conventional biotech industries?

Manpower Development in Biotechnology: National and Private Efforts[1]

One of the few countries to initiate an integrated programme of human resource development in biotechnology was India. The courses comprised post-graduate teaching programmes, short term training courses in India and abroad as also long term overseas courses to develop better faculties. The postgraduate courses were initiated in 1985 in collaboration with UGC, ICAR and the Department of Ocean Development. The curriculum contained most of the areas and elements in different institutions. The teaching programme is continuously monitored by the government to ensure minimum and uniform teaching standards. Currently the DBT is supporting seventy institutions for teaching general biotechnology, seven in agricultural biotechnology, one each in medical and marine biotechnology besides certain diploma courses in biochemical technology and molecular biology. The total student output annually is around 1000 numbers. The Indian Institute of Science (IISc), Bangalore has also been involved in selecting quality students for certain areas through written examination. All the students qualifying the DBT sponsored programmes are provided fellowships to ease the entry of meritorious but economically backward classes.

To upgrade the knowledge and research areas of interest, the Indian scientists are exposed to newer cutting-edge areas in biotechnology R&D by the DBT by offering overseas associates as well as short-term training courses. Full-fledged departments of biotechnology are being set up in various institutes all over India. Besides the efforts of DBT, the AICTE has approved B. Tech programmes in biotechnology in several public colleges/institutions. Other than higher educational institutions, expansion of biotechnology as a subject has been planned at school level also by the AICTE and UGC with the introduction of a specific module on biotechnology. The Ministry of Human Resource Development is also promoting biotechnology programs. through its instruments in various institutions. The total output of post-graduate students in biotechnology from the government endeavor is about 1500 numbers annually.

Besides government efforts, great interest has been taken by several private entrepreneurs to set up institutions to teach biotechnology at graduate and post-graduate levels. Some private engineering colleges are also offering graduate degrees (B. Tech) in biotechnology. Private entrepreneurs running teaching institutions have taken advantage of the over promotion of biotechnology by the society. The private institutes turn out nearly 5000 additional students.

The total number of biotech students turned out by the country from various institutions is around 6500, which is a sizeable number. Such students belong to the average age group of 21-25 years and they possess degrees as B. Tech or M. Sc or M. Tech or MBA in biotechnology. These students compete with several thousands other life sciences students for jobs; competition is thus becoming tough.

Although biotechnology has grown in multiple facets of human activities creating career opportunities, at present, the students passing out face stiff competition for obtaining a job. A large number works in research projects, some pursuing their PhD. They often accept under paid jobs. Many of them leave the country for better opportunities; maximum opportunity exists in U.S.A., Canada and certain European countries including UK. This situation needs serious attention. The Indian industrial sector opportunities are application oriented, requiring special skills for high paid jobs. Specialized jobs are not many; these include scale up and process development, manufacture, quality control, preclinical and clinical research, regulatory affairs, documentation and project management. Process development skills require sound knowledge in chemical and biochemical engineering. In manufacture, specialized equipment is deployed in crafted facilities; experience in handling such equipment is necessary. Quality control activities call for hands-on experience in specialized techniques and instruments handling. Clinical research is about dosage finding, dosage fixing, generating information on safety and efficacy in human subjects in specialized hospitals. Documentation for product registration is a specialized training, requiring skill in scientific writing and presentation, in accordance with legal compliance of existing rules and acts. Project managers build manufacturing facilities for biotech projects; they lead an entire project. Their expertise requires leadership for inspiring the team to accomplish the goal. They identify action items, organize meetings, coordinate and track the progress, quality and cost. Project managers should have excellent communication skills and should be able to coordinate among various departments. Project managers are not specialists but they should possess multidisciplinary skills with sound knowledge in biotechnology. In all the above areas, the presently graduated biotech students do not receive adequate skills from their institutions. The biotech industry has to spend considerable resources to in-breed the required skills. Modern biotech industry is yet at the developmental stage in India. As the industry develops, there would be more growth in trade, transport, manufacture, project management, information management, finance management and communication. Sound development of modern biotech industry shall create avenues for more jobs in India in the coming years. In the meantime, if the turnouts remain at the current rate then there may be the emergence of situations of noticeable unemployment for the biotechnology pass outs.

Scenario of Modern Biotech Products in India

India has been practicing conventional biotechnology for several decades. Products manufactured by the use of genetic engineering, immunological techniques, cell culture methods and hybridoma technology are increasingly being used during the last 15 years and local research in these areas has been intensified. The following Table 2 gives[7] the local production, imports and exports of biotech products during 2007 and the estimate for 2012.

Table 2: Local Production, Import, Export and Import as % of Local Consumption

	Sub Sectors of Biotech Products (Rs. In billion)				Total	
Product Availability Mode	**Health Care Products**	**Agriculture**	**Industrial Products**	**Other Biotech Products**	**Billion Rs.**	**Billion US $**
			2007			
Local Production	53.85	40.60	38.50	2.70	135.65	3.16
Imports	12.65	1.00	4.10	1.15	18.90	0.44
Exports	15.95	1.10	2.10	1.30	20.45	0.48
Imports as % of Local consumption	25%	2.5%	10%	45%		
			2012 (Estimate)			
Local Production	120.50	69.30	55.20	8.20	253.20	5.89
Imports	10.90	2.00	5.00	1.30	19.20	0.45
Exports	47.00	4.00	3.50	2.70	57.20	1.33
Imports as % of local consumption	12.9%	3%	8.8%	19.1%		

Health care products include vaccines, diagnostics, recombinant products and fermentation based substances. Agriculture includes traded seeds (hybrids and varieties), bio-fertilizers & pesticides, plant tissue culture and other industries. Industrial and other products include enzymes, bioinformatics, alcohol & fermented beverages as well as research chemicals used in biotechnology work.

The main indicators from the above table are the trend of increase in local consumption and decrease in imports over the years. Local consumption, which is the total of local production and imports minus exports, shall be on significant rise; the quantum of imports as the percentage of local consumption shall decrease over the years. These are indicators of brisk industrialization in biotechnology.

In agriculture, insect-resistant Bt-cotton was approved for cultivation in the country in early 2002; this wise decision contributed significantly to increase in the cotton lint production and improved its quality. This had also contributed to sizable reduction in the use of chemical pesticides. The crucial transgenic components of the technology were imported from three countries, namely USA, China and Japan; the insect –resistant trans-genetic trait was introduced in several Indian hybrids that made the difference. During 2007-08, nearly 1·4 million acres of land were brought under the cultivation of Bt cotton using locally produced seeds worth 10200 million rupees[8]; cotton lint production registered 31.5 million bales.[9]

Modern biotechnology is rather new to India. There is little doubt however, that the applications of modern biotechnology would increase very fast, as the products or processes hold great potential for providing much better solutions to improve the health of people or the quality of life, improve agricultural productivity significantly along with supplying more nutritious food, produce industrial bio-products at much cheaper prices and improve the quality of environment more effectively on a sustainable basis.

Indian Capabilities in Modern Biotechnology

Coming back to Indian developments, while by the end of 2007 there existed over 900 companies operating in all sectors of biotechnology, there were only about 60 companies that were working in modern biotechnology.

None of the Indian companies have introduced any significant biotech product of original research in Indian market that could be considered as unique, introduced for the first time in the world. But some have introduced known products that tantamount to effective imports substitution. Some others have teamed up with foreign companies for sourcing technologies and are experimenting with new products produced by foreign technologies with a view to introduce them into the Indian market within the framework of Indian laws. Certain companies are also introducing novel and effective but non-IPR protected genes in to Indian germplasms to increase agricultural productivity or to reduce production costs. All these conditions and situations are satisfactory to begin with, but the country has to go a long way to come up with innovative products that would be original and that would have cutting edge impact in the global context. The existing scenario depicts considerable lack in basic research and inadequate long term planning in the industry. Why is such a scenario emerging?

Ideas and innovations surface from insights and observations of individuals imagining novel possibilities and making challenging conjectures. Such situations are encountered, among other reasons, under conditions of extreme stress, where sustainability and survival conditions are at stake. This is not yet the condition in the biotech R&D sector of the industry in India in the global context.

Indian biotech industry with significant turnover has to inculcate talented individuals to prepare for harnessing opportunities, for which the key persons have to be knowledgeable and well informed about the innovative platforms with profound acquaintance of global developments. Concomitantly, the industry cannot be shy of investing heavily in potential areas of basic research, where possibilities exist for applications. It is futile for the industry to pursue basic R&D where applications are not in sight; the team leaders have, therefore, to be carefully chosen who have a knack for applications. For becoming an innovative company, the individual industry has to have patience and would have to distinguish between intangible assets and R&D costs.

Production: The modern biotech products are only a few, which are being produced currently in the country. They include the following in various biotech sectors [1, 2, 10, 11and 12] (Table 3).

Up to the October 2008, twenty-two recombinant drugs (Table 4) have been approved [7, 12] for marketing in India, of which only eleven are being manufactured as indicated in Table 3.

Table 3: Modern Biotech Products Currently (2006-07) being Produced in the Country

Sector	Major Industries Producing with Remarks
Health	
Hepatitis B surface antigen based Vaccine	Transgene Biotech, Hyderabad conducted first experiments in the country using recombinant *Hansenula polymorpha.* Technology belonged to Rhein Biotech, Germany. Shantha Biotechnics, Hyderabad used recombinant *Pichia pastoris* for this. Osmania University and CCMB both at Hyderabad and other assistance taken by co. Wockhardt Ltd. Aurangabad used recombinant yeast strain of *Hansenula polymorpha.* Technology belonged to Rhein Biotech, Germany. Bharat Biotech International Ltd., Hyderabad produced in *Pichia pastoris.* Assistance from IISc, Bangalore. Panacea Biotech Ltd., Delhi used recombinant *Pichia pastoris.* The technology belonged to CIGB of Cuba. Serum Institute of India Ltd., Pune used recombinant *Hansenula polymorpha.* Technology from Transgene Biotech, Hyderabad. Biological E Ltd., Hyderabad produced the substance using recombinant *Pichia pastoris.* The technology was obtained from the IISc, Bangalore.
Granulocyte Colony Stimulating Factor (G-CSF)	Dr. Reddy's Laboratory developed the technology using transformed *E. coli.* The technology was developed in-house. Intas Ltd. Ahmedabad also developed the technology in *E. coli.* The technology was developed in-house. Several other companies are developing the technology while many are importing & selling. Biocon also producing.
Recombinant Erythropoietin	Wockhardt Ltd. Aurangabad producing using modified CHO cell line. It was an Italian technology. Intas India Ltd. Ahmedabad is also producing it. The strain was procured and technology perfected in-house. Efforts being made by several others. Also, there are direct importers. Many are formulating product by importing bulk.
Interferon alpha 2B & pegylated product	Shantha Biotehcnics Ltd. Hyderabad developed the products in *E. coli* strain. The technology was developed in-house. Efforts by several other newcomers as well as introduction of the product by direct importers. Several companies are trying to develop the pegylated form of the product.
Epidermal Growth Factor	Bharat Biotech Ltd. Hyderabad developed the product in E. coli. The technology was developed in-house with assistance from IGIB scientists.

Table 3 continued

Table 3 continued

Streptokinase	Shantha Biotechnics, Hyderabad; Bharat Biotech, Hyderabad & Biocon, Banglore developed this technology in *E. coli*. The recombinant product is inherently unstable and stabilization is tricky.
Recombinant Human Insulin	The product was developed in *Hansenula polymorpha* by Wockhardt India Ltd. The basic technology was procured from Rhein Biotech, Germany. The product was developed in *Pichia pastoris* by Biocon India Ltd. The strain was procured from Shantha Biotechnics, Hyderabad. Efforts by several other newcomers as well as introduction of the product by direct importers. Several Indian companies are trying to develop the basic technology.
NIMOTUZUMAB	Biocon Ltd. Bangalore has launched a monoclonal antibody produced by genetic engineering method, which works to block certain receptors of epidermal growth factor that are responsible for proliferation of cancer cells. The technology belongs to Cuban Centre of Molecular Immunology. Biocon received the rights for the product in India.
RITUXIMAB	Dr. Reddy's Laboratory, Hyderabad has introduced the product based on local production and purification. The product is indicated for treating Non-Hodgkin's Lymphoma and Rheumatoid Arthritis. The technology and the recombinant cell line were procured from U.S.A.
Several New Products & Bio-Generics	Many companies are working on different compounds with/without collaborations to develop the generic products and to market them.
Agriculture	
Bt Cotton	**Private Sector**
	Mahyco-Monsanto (MM), a sister concern of Monsanto Inc., USA and Maharastra Hybrid Seeds Company Ltd., (Mahyco) Jalna obtained approval for producing Bt cotton seeds containing *Cry1Ac* gene (MON 531 event) in March 2002 and started selling. Later, they introduced seeds containing two genes namely *Cry1Ac* & *Cry2Ab* from event MON 15985. Company also working to generate herbicide resistant plants using CP4 EPSPS gene of Monsanto USA. Hybrid Bt-cotton seeds were introduced through Mahyco. MM sub-licensed several companies namely Rasi Seeds Company Ltd., Nuziveedu Seeds Co. Ltd., Hyderabad, Tamilnadu, Nath Seeds Ltd. Aurangabad, Ankur Seeds Ltd., Nagpur, Krishidhan Seeds Ltd., Jalna, Ajeet Seeds Ltd., Aurangabad, Ganga Kaveri Seeds Pvt. Ltd. Hyderabad, Tulasi Seeds Pvt. Ltd., Guntur, Prabhat Seeds

Table 3 continued

Table 3 continued

	Ltd. Hyderabad, Emergent Genetics, Hyderabad, Vikram Seeds Pvt. Ltd., Ahmedabad, Pravardhan Seeds Ltd., Hyderabad, Vikki Agrotech Pvt. Ltd., Hyderabad, Prabhat Agri biotech Ltd. Hyderabad, Vibha Agrotech Ltd., Hyderabad, Nandi Seeds (P) Ltd., Ahmedabad, Pro Agro Seeds (P) Ltd., New Delhi, Namdhari Seeds (P) Ltd., Bangalore, Bio Seeds Research, Hyderabad, Vibha seeds (P) Ltd., Hyderabad, Proagro Seeds Co. (P) Ltd., Gurgaon, Amar Biotech Ltd., Hyderabad, Bayer Bioscience Pvt. Limited, Hyderabad, Seed Works India Pvt. Ltd, Hyderabad and Solar Agrotech Pvt. Ltd., Rajkot to use Bt-*Cry1Ac* (MON531 event) in their non-Bt cotton lines. MM also licensed several companies to produce Bt-cotton hybrids containing two genes namely *Cry1Ac* & *Cry2Ab* from event MON 15985 to Mahyco, Krishidhan, Ajeet, Nuziveedu, Rasi, Amar Biotech, Anjur, Bayer, Bioseeds, Ganga Kaveri, Kaveri, Monsanto Genetics Pvt. Ltd., Mumbai, Nandi, Prabhat, Tulasi, Vibha, Vikarm and Namdhari.
	Nath Seeds Ltd. Aurangabad obtained cotton seeds containing insect resistant genes named as " GFM *Cry1A*" containing a fusion of Bt-*Cry1Ab* & *Cry-1Ac,*. The stable hybrids are being sold. The technology was procured from Biocentury Transgene Company, China. Nath also sold the technology to Navkar Hybrid seeds Pvt. Ltd. Ahmedabad, Uniphos Enterprises, Vapi, Yashoda Hybrid Seeds Pvt. Ltd., Hinganghat, Zuari Seeds Ltd., Bangalore, Green Gold Pvt. Ltd., Aurangabad and Safal seeds & Biotech Ltd., Mumbai for producing Bt-hybrids.
	Syngenta India Ltd., Pune has introduced insect resistant cotton seeds containing Vip-3 gene. The stable hybrids are being sold. Syngenta India obtained the original technology from its parent company.
	JK Agri Genetics Seeds Ltd., Secunderabad, purchased transgenic seeds containing Bt-*Cry1Ac* gene (event 1) from BREF-Bioteck, IIT, Kharagpur & UDSC New Delhi to produce Bt-hybrids, which are being marketed. The technology was developed at IIT Kharagpur by BREF-Biotek & UDSC New Delhi.
	Public Sector Institutions
	Central Institute for Cotton Research, Nagpur has developed plants resistant to lepidopteran pests using Bt. *cry* genes. Transformed cotton Bt BN Variety has been introduced.

Several companies are also importing the above products besides supply through the local manufacturers. The solely imported eleven products were approved for sale, based on data on clinical trials generated out side India.

Table 4: Recombinant Therapeutic Drugs Approved for Marketing in India

S. No.	Molecules	Therapeutic applications
1.	Hepatitis B vaccine (r- HBsAg based)	Immunization against Hepatitis B virus
2.	Granulocyte Colony Stimulating Factor	Treatment of neutropenia
3.	Erythropoietin	Treatment of anaemia
4.	Interferon alpha 2B	Treatment of leukemia, Hepatitis B and Hepatitis C
5.	Epidermal Growth factor (EGF)	Organ morphogenesis and mitogenesis
6.	Streptokinase	Dissolution of clot in acute myocardial infarction
7.	Human insulin	Treatment of diabetes
8.	GM-CSF	Chemotherapy induced neutropenia
9.	Interferon alpha 2A	Chronic myeloid leukemia
10.	Human growth hormone	Treatment of dwarfism in children
11.	Nimotuzumab	Treatment of breast cancer
12.	Rituximab	Treating non-Hodgkin's lymphoma & arthritis.
13.	Tissue Plasminogen Activator	Dissolution of clot in acute myocardial infarction
14.	Blood factor VIII	Treatment of haemophilia type A
15.	Follicle stimulating hormone	Treatment of reproductive disorders
16.	Teriparatide (Forteo)	Parathyroid hormone for treating osteoporosis
17.	Drerecogin alpha (Xigris)	Burns and severe sepsis
18.	Platelet Derived Growth Factor (PDGF)	Receptor antagonist in certain types of cancer
19.	Interleukin 2	Treatment of renal cell carcinoma
20.	Blood factor VII (Eptacogalpha)	To control bleeding in hemophilia patients
21.	Interferon gamma	To treat chronic granulomatous disease & osteopetrosis
22.	Interleukin 11	To treat thrombocytopenia (Platelet reduction)

Research & Development: Basic research in modern biotechnology is mainly in public funded institutions. Industry is substantively in areas of applications. In healthcare, some institutes are trying to develop generic biopharmaceuticals and novel methods of delivering them; a few are engaged in drug designing and software development, utilizing techniques of bioinformatics. In agriculture [5, 10 & 11], research is pursued for the development of genetically modified rice, potato, tomato, corn/ maize, brinjal/eggplant, mustard, pigeon pea, cauliflower, cabbage, chickpea, groundnut, black-gram, wheat, banana, coffee, muskmelon and tobacco. Both private and public institutes are in research. Different kinds of transgenic nucleic acid constructs are being handled. The genes are mainly out sourced. Some analogues have been constructed based on available literature and individual skills to derive economic advantage in cultivation. Several institutes are working to produce enzymes from recombinant organisms; the products and processes being developed are for xylanase, different kinds of proteases, lipases, cellulases, amylases, phytase and rennin (for cheese making); certain enzymes for molecular biology research are also being worked upon. The efforts certainly need more spread and dispersion. Besides pursuing more avenues for applications, basic investigations to tackle serious problems in health and agriculture should be undertaken in a focused manner.

The global picture of production and use of modern biotech products is very wide. The major health care products already approved globally[13] with their annual sales turnover is placed below in Table 5.

Table 5: The Global Major Biotech Products Market by Class 2001, 2002, 2005 and Projections for 2010

Class	Sales 2001 ($m)	Sales 2002 ($m)	Sales 2005 ($m)	Estimated Sales 2010 ($m)
Erythropoetins	6,702	8,426	12,815	17,350
Interferons	3,923	5,731	6,635	8,470
Insulin	3,949	4,400	5,800	10,340
Monoclonal antibodies	2,997	4,150	9,120	18,200
Blood factors	3,188	3,565	4,985	6,360
Colony stimulating factors	2,059	2,739	4,630	5,910
Growth hormones	1,652	1,703	1,860	2,050
Interleukins	173	213	390	630
Growth factors	108	123	180	360
Therapeutic vaccines	50	68	170	340
Others (calcitonins, enzymes, TNF, etc.)	2,080	2,222	2,600	7,000
Total	26,881	33,340	49,185	77,010

The actual sale of top 25 biotech companies in the world for the year 2005 was reported to be US $ 40 billion[1], which is about 82 per cent of the global sales for the year 2005. This indicates that the biotech products are monopolized within a very small number of players and would remain so for some time in the future till there is adequate global development and dispersal.

The global monopolistic situation needs to be studied and understood in order to improve the local situation in India. Monopoly comes mainly from IPR; IPR-protected products are the gifts of intense research.

In order to understand the dynamics of research across the world, it is necessary to analyze what research work is presently going on across the globe. The developments taking place globally in terms of progress of emergence of new products in various areas in the health care products arena is described below[14] in Table 6.

Table 6: Number of Biotechnology Drugs in Development

Biotechnology Medicines Under Development by Therapeutic Category (Upto Dec. 2006)

Therapeutic Category	No of Drugs
AIDS/HIV/Infection/Related Conditions	22
Autoimmune Disorders	44
Blood Disorders	10
Cancer/Related Conditions	210
Cardiovascular Diseases	22
Diabetes/Related Conditions	15
Digestive Disorders	14
Eye Conditions	6
Genetic Disorders	9
Growth Disorders	4
Infectious Diseases	50
Neurological Disorders	17
Respiratory Disorders.	13
Skin Disorders	7
Transplantation	4
Other	18
Total	465

In 2007, more than 100 new biotech drugs have been marketed globally. Wide ranges of biotech drugs are under development as shown above; major R&D work is being carried out in U.S.A. In India no new R& D stage product has yet emerged that would qualify to be rated as unique that has potential for making significant impact globally.

In agriculture, efforts to develop GM plants and planting materials are being made in India as has been indicated earlier. The global development is moving much faster and several types of genetically modified plants are being invented that are safe to the environment as also the food products produced from them are safe to consume. Such developmental work is a continuous process and if India wishes to take advantage from them, extensive alliance[15] may have to be created till the local capabilities are sharpened. The strength of India lies in its genetic biodiversity as well as several parental lines developed in agriculture that are proven to be more efficacious in productivity and resistance to stressful conditions. Therefore, incorporation of more favourable transgenic traits in them would benefit Indian agriculture considerably. The question is why Indian development is not matching the global competition.

It would be evident from the above that in all the sub-sectors of modern biotechnology India has to make more progress in basic research as well as in applications in new biology, to catch up.

Future Trend and Interventions in Biotechnology

India already has developed competence in selected areas that provide the entrepreneurs an edge over other developing countries to set up viable and competitive biotech industry in certain areas. Indian Government continues to play a significant role in the promotion of biotechnology in all its facets. The efforts of DBT during the initial years in transferring institutionally developed technologies to the industry have been summarized.[16, 17] These efforts have been instrumental to developing competence mainly in the conventional biotech products.

Existing and new entrepreneurs shall be expanding their activities and entering in to the bio-similar or bio-generic products in health care area and in genetically modified plants, (using available genes and constructs) in agriculture. Indian productive parental lines for hybrids and varieties (for self-pollinated crops) shall be extensively utilized in producing GM plants using borrowed genes, in agriculture. Expansion shall also be taking place in conventional biotech activities in all sectors of biotechnology. The deployment of the existing mindset in a background of almost non-existing basic research infrastructure at sites of the existing industrial premises would not enable or encourage them to put efforts to invent or discover such new products that would have sales of jackpot kind (annual sale more than 1billion US dollars). With sound expertise already existing in the deployment of microbial fermentation processes and with modest capabilities in downstream processes for recovering milligram or microgram quantities of metabolites from liter quantities of fermented broth using, especially standardized micro-filtration and chromatographic techniques as well as membrane filtration methods, where for products or processes deployment very little basic research inputs are contemplated and where complex product characterization services requiring inputs from sophisticated instruments such as RP-HPLC, MALDI-TOF, DNA sequencing, capillary gel electrophoresis, etc. are available on hire, many entrepreneurs shall invest in several value added bio-pharmaceuticals, which are expected to be produced in sizeable quantities locally. Concerted efforts would be made especially for products where the selling prices are several times higher than their manufacturing costs and the availabilities are still in the hands of a few foreign companies that are yet monopolizing the world market, while the product patents have expired on them or are on the verge of expiry. There would be crowding of several companies in such endeavour and once in into the business endeavour, several of such entrants shall invest in R&D in order to become more productive. It is anticipated that the market competitiveness and the compulsions to remain efficient shall drive sizeable investment in creating R&D capabilities in biotechnology in the industry sector. This situation shall be fuelled and stimulated by several government departments and institutions by extending assistance by providing seed capital to certain classes of activities and entrepreneurs. It is not yet clear if such strategies are adequate.

India has to have more healthy people to face the global competition. Several neglected diseases of the poor including tuberculosis, malaria, diarrhea, trypanosomiasis, dengue, leishmaniasis and lymphatic filariasis are responsible for many man-day losses in productivity. Indian biotech R&D has to address these problems in public funded institutions and come out with robust solutions. In other major areas that contribute to significant loss of man-days such as diabetes, cardiovascular diseases, cancer and mental health disorders, efforts should be made through policy interventions to have access to current biotech drugs to treat these disorders. Transgenic substances have potentials for raising the efficiency in agriculture and food availability. Basic research in public funded institutions needs to be stepped up in strategic areas; these include development of novel genes, promoters, selectable markers, protocols for plants and animals transformation & regeneration, field testing & performance evaluation, environmental and food-safety evaluation, etc. General public has to be made aware and knowledgeable by the government regarding crops and foods improved by the application of genetic engineering. Regulations have to be coupled with sound science and societal interest factors to speed up the decision making process for the commercial use of GMOs on a precautionary principle.

Concluding Remarks

India may emerge as a strong industry in biotech products in the coming years. The scenario shall manifest dominance in the conventional biotech products. The local consumption shall also rise substantially. The patent expired biotech products shall be the mainstay of modern product portfolios. In agriculture, many stress tolerant genes shall be inserted into Indian plants to produce, say pest-resistant plants. Large quantities of enzymes produced from GM organisms shall be in the market.

Conventional biotech industry shall grow fast and sizably in the present business environment. Such products shall meet the local demand and a portion shall get exported too. Recombinant DNA products shall be exported from among the generic biotech segment, where product patents have expired. But the markets in the developed world would not be easily accessible; the industry and the government may have to closely work to ease the process.

There are indications that productivity in agriculture is required to be raised fast; use of GMOs can contribute to the process. Transgenes may be IPR-protected elsewhere. But India has strong foothold to negotiate for authorizing the use of its genetic parental materials, where trans-genes would be inserted. In the background of increasing food prices and large subsidy in agriculture, the exploitation of GM-plants and seeds may be examined on a case-by-case basis, and the commercial introduction process be hastened.

Large sum has been spent in the public institutions. The industry is setting up more basic facilities for biotechnology. More money shall, therefore, be channeled towards industrial R&D for which the basic research has to move up. Innovation is the creative ability of transforming basic understanding into applications. India needs more of innovations in that sense of the term both in its institutions and in industry. The country shall have expectations from such innovations to have some star products emerging. Wisdom lies in taking more proactive steps to develop a globally competitive local industry that stands on solid foundation of basic research. Facilitation of biotech industries no doubt makes economic gain; but modern new products should also emerge. Otherwise, the achievements would continue to look small before the world developments where companies are moving ahead skillfully with more concerted efforts, after the human genome sequence was unveiled in 2002 to read the "Book of life" chapter by chapter to bring in better solutions in several facets of modern biotechnology. Forging strong alliance among the Indian industry and the public institutions should make a difference for the country in the global context.

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Technical Capacity, Policymaking and Food Standards: An Overview of Indian Experience

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Abstract: The SPS Agreement in the WTO gives legal validity to the CODEX standards. Since the developed countries have been at the forefront of setting the food standards in the CODEX, the developing countries have been increasingly engaged in the CODEX, and also in the WTO, with an objective to increase their exports of the agricultural and food products. But such objective and desire have often been stymied by the lack of institutions which can sustain the intense technical negotiations at the CODEX. If these participations are not qualitatively satisfactory, the very objective of such participations is not fulfilled. But since most of the developing countries are lacking in such high technical capacity, they are unable to influence or qualitatively shape the negotiations in the CODEX. This also impacts their exports of agricultural and food products.

India has been an active member of the WTO. But whether it has been able to influence or respond to the play of events internationally and concomitantly balance it with the domestic imperatives that are embedded in the international legal and technological regimes, institutional capacity constraints and other social issues. This paper examines such issues, and also examines some bilateral trade agreements which demonstrate the mounting pressure on the developing countries to conform to the food standards of the developed countries.

Keywords: SPS Agreement, Food safety standards, Technology, Bilateral Trade Agreements

Introduction

The international debate and discourse on food standards in the last two decades have been punctuated by a number of public health controversies and international trade disputes resulting at times in trade embargoes (Isaac and Kerr, 2003). These debates have also been

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characterized by an increasing involvement of the civil society in questioning both the procedural and the distributive impacts of food standards setting and their implementation. The discourse has, therefore, been highly politicized given the high stakes that are involved in the regime setting and its operation.

Primary reason for the above change has been the international regulation of food standards that has been recognized and given legal validity by the international trade regime of the WTO. The focus of debate has also intensified due to rapid lowering of the tariff barriers as the focus is shifting to the non-tariff barriers to trade like sanitary and phyto-sanitary measures and other technical regulations.[1] This has resulted in polarization - a broad international fault line between the developed and the developing countries, with the former alleging non-adoption of international standards on food safety by the developing countries and the latter countering them with arguments relating to the usage of such standards as disguised restriction to trade in the form of lack of financial and institutional capacity for the developing countries to be involved in regime setting and its national implementation.

If we look closely on the above positions on international food standards governance, we find that there are mainly three sites of contestations; the first is the CODEX itself, wherein the international norms and guidelines are being formulated; the second one is the WTO, wherein CODEX non-conforming national regimes can be legally challenged through the dispute settlement process; and the third one (and also perhaps the most dynamic and most interesting) has been the bilateral trade agreements between the two largest trade blocks (viz. the USA and the EU) and the developing countries.

The first site has been in a legitimacy crisis of sorts partly because of the increasing pressures of negotiating a legal regime through an institution which has a philosophy based on consensual decision-making and that is not structurally constructed to provide for equity in participation. In other words, the institutional process of the CODEX has been exposed to mounting criticism but the process itself was not put into place in the first place to address the increasing claims being made onto it through the WTO mandate that was extended to it. In that sense, there is a case of disjuncture between the institutional objectives and the processes on which CODEX was set up and the extensive demands which were made upon it post-1995 (after the establishment of the WTO) through the recognition given to it under the legal agreements of the international trade regime of the WTO.

The second site is of the WTO which is organically linked in terms of its operation in extending legal validity to the regime emanating from the CODEX. Though the disciplines are institutionally linked, both the negotiation process (to a limited extent) and the dispute settlement apparatus within the WTO have been extremely dynamic in terms of two things. First, through the negotiations within the WTO, developing countries have made a substantial pitch for revisiting (though to a limited extent) the CODEX policymaking process (Zarrilli and Musselli, 2004). Second, the dispute settlement process has also contributed to this process in terms of clarifying and developing disciplines that have partially responded to the disjuncture that the post-1995 trade regime has forced upon the international food policy regime in general.

In contrast to the above, the third site perhaps is the most dynamic as well as being the one exposed to high drama, given the closed nature of bilateral international relations and lack of public engagement in general. Two largest trade blocks, the US and the EC have engaged in extensive bilateral treaty making driven by the need to co-opt trading partners to adopt standards mirroring their own domestic regime. The bilateral trade agreements between the two trading blocks and their developing country trading partners have come to be increasingly used to export food safety standards regulation. The trading arrangements provide adequate arenas since the basket of measures are large and, therefore, provide flexibility and allow pressure tactics to be deployed to a considerable extent. Further the one-to-one negotiations procedure is also ideal, since structurally it is susceptible to pressure tactics.

All these three sites are also characterized as sites of contestations in their own right, since each display characteristics of individual activity and, therefore, offer a chance for compromise. However, all three sites are also dialectically linked together, since each may support, influence or even provide competition to each other in terms of member countries using each forum to influence policymaking.

Given the above context, this paper examines the three sites of debates. It also highlights developments within the national scene, which are bound to influence international developments and which may also be influenced by the other. In conclusion the paper gives a brief background of the domestic food safety regime and highlights a particular instance of a sudden shift in policy, which clearly seems to suggest international pressures emanating from bilateral trading partners.

Negotiations on Food Standards within the CODEX Alimentarius Commission

The most important international agency in the arena of food standards is the *Codex Alimentarius* Commission or CAC. The WHO and the FAO, as it is popularly known, set up CAC jointly in 1963. The CAC was set up primarily as a coordinating agency to facilitate the setting of standards on food safety and ensure certain standardization in food trade practices. The membership was and continues to be open to all FAO and WHO members with a large number of international NGOs having observer status.[2] The organization functions through a network of regional, commodity specific and general committees that deliberate on standards. The committees are organized horizontally (general issue areas), vertically (issues that are specific to some commodities) and in regional committees, which are aimed at enabling regional consensus building on region specific standards and issues.[3]

Before the coming into place of the WTO agreements in 1995, the deliberations in CODEX used to be largely consensual and non-posturing in nature. The organization was essentially used as a forum for discussing and debating scientific information, developing regulatory best practices and exchanging and dissemination of information on country practices in the domain of food standards. Direct adoption of the standards produced by the CAC was at best limited amongst countries.[4] The coming into place of the SPS/TBT Agreements has had a crucial impact on the functioning and authority of the CODEX.

Post WTO Codex standards carried within a presumption of legality under the SPS/TBT Agreements. Thus countries adopting CODEX standards were presumed to be in conformity with their WTO obligations.[5] Though this did not demand strict conformity with the CODEX standards, countries could only justify their non-adoption by adhering to strictly defined criteria. The high costs of litigation in the WTO also meant that adherence to the CODEX standards was a more cost effective alternative and avoid getting embroiled in disputes within the WTO. Thus, the CODEX standards not only received legal validity via its inclusion in the text of the SPS/TBT Agreements but also the organizational and functional costs of participating in the WTO meant that there was/is a real (albeit negative) incentive in the adoption of these standards (Appleton, 2000). Another important aspect of the legal effect of the CODEX is the definition of international standards includes standards, guidelines and recommendations.[6] In this context one could safely draw the conclusion that the SPS extends legal validity to all recommendations of the CODEX without any differentiation.

Post WTO has also witnessed the growing importance of the CODEX standards. However, it has also been subjected to a slew of criticisms focusing on systems of participation for members, processes of deliberation, etc.[7] Various committees operating under the CODEX are hosted by the individual governments. The host country member has a significant leeway in agenda setting within the committee. Further, the increasing use of the voting system to adopt standards within the CAC (in lieu of a consensual process) has also contributed to the legitimacy crisis facing the CODEX. Moreover, developing countries also complain that standards in developed countries are in some instances more stringent than the CODEX standards (Brack, Falkner and Goll, 2003), and, therefore, there is always a pressure within the CODEX to continuously upgrade standards to more stringent level. One of the reasons for this is the slow pace of standards development within the CODEX and the faster pace of standards development in developed countries.[8] This has led to a viscous circle having a spiraling effect on stringency of the standards given the developed countries wariness to downgrade standards within their domestic jurisdictions.

The CODEX in the post 1995 phase, after it was referred to as an acceptable standard benchmarking agency by the WTO, has, therefore, witnessed widening and deepening of the negotiations taking place within it. In terms of subject matter the number of food standards deliberated within the CODEX has increased exponentially over the last decade. Also the nature of factors and criteria underlying a scientific standard has also proven to be a point of contention in the CODEX. The Procedural Manual of the Codex Commission differentiates between risk assessment and risk management with reference to food standards.[9] It defines risk assessment as purely a scientific process and the latter as a policy process that includes consultation with a range of interested parties and weighing of alternatives. This kind of a divisive frame of reference is organically linked with that of the acceptance of the role of "other legitimate factors" within the decision-making framework of the CODEX – meaning within the domain of risk management. The manual provides for several caveats in the operation of "other legitimate factors", viz. putting an additional burden on managers to "indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related text". It further stipulates that the consideration of these factors "should not affect the scientific basis of risk analysis", thereby clearly extending primary importance to scientific outputs from the risk assessment, over that of "other legitimate factors". Moreover, it considerably limits the scope of "other legitimate factors" by specifying that only those factors that have a world-wide/regional basis should be incorporated (thus negating territorially limited factors that may have an impact nationally). Singularly the manual exhibits some awareness of the challenges faced by developing countries in undertaking risk assessment and states that *"particular constraints of the production or processing methods, transport, storage especially in developing countries may be considered"*[10] (emphasis added). In this case, therefore, the manual makes an exception and uses non-obligatory language and in effect substantially waters down the legal effect of the aforementioned section.

One horizontal issue that has proved to be contentious within the CODEX is the definition and scope of the "precautionary principle". The lack of agreement between members has resulted in a compromise leading to the adoption of the following position in 2001: "When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by available scientific evidence". This is indeed problematic especially given that the WTO does not differentiate between standards, codes or guidelines. Thus, the legal validity of a "code of practice" emanating from CODEX would be akin to the standards or guidelines proscribed by it under WTO law.[11]

Another important area of discussion has been the definition of "other legitimate factors" in the context of the decision-making within CODEX. Discussions on this issue have been divisive and there is yet to be an agreement on what constitutes "other legitimate factors". However, the statement of principles provides for certain critical caveats that will have an import on the discussions and could very well limit its scope. First it reiterates the separation between the risk assessment and the risk management processes in order to secure the sanctity of the former and ensure that it only has a scientific basis. It also states that CODEX will consider only those factors which have a regional or a worldwide reach and not those that are territorially limited within a nation state. Thus, the geographical reach or scope of the factor is an important prerequisite for its consideration within the CODEX. Further, the Statement also takes into account the particular circumstance of the developing countries in evaluating the feasibility of the risk management preferences that are adopted within the CODEX, thereby providing for a consideration of extraneous factors – "other legitimate factors" in negotiating and mandating standards. It also stipulates that in the case of forwarding of economic interests and trade issues which are considered to be germane to standards setting within the CODEX, quantifiable data should be made available to support them.

The above discussion highlights some of the tensions, which are prevalent within the various committee negotiations in the CODEX. There have been concerted efforts on the part of developed countries to push for an exclusively "science based" risk management techniques. However, this assumption has been questioned by social scientists and management theorists who have denied the claims of neutrality of science (Walker, 2003) and have reiterated the non-scientific aspects of determination of standards of risk. Criticisms of the CODEX have also been targeted at the inequalities of participation embedded within the functioning of the various committees and task forces.[12] The report of the evaluation of CODEX has also commented on the growing frustrations of the LDCs and the developing country in fully participating in the deliberations of the CODEX.[13]

Legal commentators like Livermore have sought to characterize such tensions as a "legitimacy dilemma" faced by the CODEX resulting from the expanded organisational mandate backed by the international institutional mechanism of the WTO. [14] He has highlighted the change in the nature and political culture of the negotiations within the CODEX, given the high stakes. From an external perspective this also means that the CODEX negotiations have attracted considerable criticism from the international civil society. Livermore also points out that the WTO agreements provides for a balancing of interests given the separation and the institutional differentiation of powers. He calls this "institutional differentiation" and understates its importance in functioning as a balancing of interest mechanism, and then goes on to argue that the judicial review function of the WTO tribunals (Panels and the Appellate Body) enables it to undertake a procedural review of standards setting activities within the CODEX. In defense of this contention he marshals jurisprudence from the *EC-Sardines* case[15], wherein the AB had undertaken a review of the internal decision-making processes of the CODEX. He has also demonstrated that the developments of administrative law principles like due process and transparency requirements have come to characterize Appellate Body deliberations.[16] In this context main thesis is that the Appellate Body is empowered to review CODEX decisions on the basis of transparency and other procedural bars that would to an extent address the claims of a crisis of legitimacy brewing within the CODEX.

Bilateral Agreements and Its Influence on Food Safety Standards

> *"Our SPS standards are not open to negotiation, and they apply in full to all trade: preferential as well as non-preferential."*
>
> — European Agricultural Commissioner Mariann Fischer Boel (Sixth Meeting of the International Centre for Advanced Mediterranean Agronomic Studies, CIHEAM)

This comment perhaps best illustrates both the inflexibility and also the resolve of the EU (mirrors that of the USA) to influence trading partners to grant the same level of protection and also to adapt (and in most cases transpose) their domestic food safety framework to match the EU/USA regimes (Paarlberg, R, 2002). In this section we would study two such examples of bilateral trade agreements - EU-Chile Association Agreement and the United States-Panama Agreement that have a well-detailed chapter on SPS standards. [17] From these chapters it is apparent that they have been negotiated keeping in mind the EU/USA standards. These two agreements are both similar and dissimilar in certain aspects. They are similar because, they represent the intense drive of these two trading nations/community to push for harmonization of SPS standards. However, they are starkly different in their choice of methodology. The EU-Chile Association agreement focuses largely on laying down structural linkages between the regulatory systems of the two countries – enabling close cooperation both the formation and operation of SPS measures and mechanisms. The US-Panama agreement, on the other hand, is more direct in its approach, where the US uses its historical linkages with its neighbouring countries like Panama to push through an extensive equivalence project that effectively narrows down the room for maneuver (respond to their own domestic priorities and conditions) to partner countries like Panama.

(a) EU-Chile Association Agreement

At the time of its signing the EU-Chile Association Agreement was one of the most far reaching agreements as it clearly went beyond the traditional areas associated within trade agreements. As the name suggests – the association agreement – is designed to be comprehensive and cover a wide range of social, economic and technical cooperation. The inclusion of trade as one of the issues covered within the agreement influenced the coverage of trade issues within the agreement itself. Analysis of the agreement reveals that the provisions were a far-reaching extension in providing for close regulatory cooperation between the authorities of the two countries so as to preempt any conflict of interest in terms of their sanitary and phytosanitary standards. Thus, addressing trade issues through an association agreement provided an avenue to push for closer regulatory cooperation on trade issues.

The section on equivalence is comprehensive and is integrated into Annex IV of the Agreement. The provisions provide for strong cooperation between the Chilean and the EU authorities in standards, technical regulations and conformity assessment. Further, the agreement also identifies international and European standards as benchmarks to which Chilean standards should be based on (Christoforou, 2004). This also illustrates drive for the integration of the EU standards into the agreement along with international standards, which are recognized under the WTO Agreements. The agreement also puts into place stringent conformity assessment structures and procedures as conformity assessments are popular tools within association agreements in stimulating greater oversight and monitoring and evaluation of regulatory measures within the domestic jurisdiction of trading partners.

The development of animal welfare standards in particular received special attention within the Association agreement. Articles 2, 3 and Appendix 1c deal with the stunting and slaughter of animals. The preamble of Annex IV of the agreement specifically mentions the development of an international animal welfare standard as one of the aims of the Association agreement. This in itself is not incongruous with the current policy of the OIE (World Organization for Animal

Health), which has sought to focus actively on the development of animal welfare standards. However, what requires attention is that of placing such an aim within the standard aims of the agreement itself. In this context the agreement itself becomes a vehicle for harmonization and also a site for active negotiation on the development of "international standards". Further, the terms and broader contours of such future negotiations would be circumscribed by the provisions of the agreement. The agreement thus binds the parties to future negotiations on international standards that go much beyond the dictates of multilateral negotiations within the WTO.

Lastly the agreement is also characterized by the strong periodical institutionalized forms of information exchange and refers to regulatory convergence and compatibility between the domestic regimes of the trading partners. This direct reference to convergence and compatibility is not surprising given the aims of the association agreement. Further, the institutionalized nature of information exchange and mechanism for cooperation anticipates domestic regulatory changes and equips the partners to provide for advanced notice of such changes and more onerously the need to take into account the views of the trading partner in envisaging and developing domestic regulatory regimes in related areas. This in a manner legitimizes and leverages the role of trading partners from that of external influencing domestic regulatory policy to that of demanding attention and consideration of their viewpoints in decisions governing the domestic policy regimes. This conceptually radicalizes their involvement and influence to influence and shape policy making nationally.

(b) The United States-Panama Trade Promotion Agreement

The US-Panama TPA was signed in June 2007, after three years of protracted negotiations between the two sides. Soon thereafter the Panama government got a swift approval of their legislature with an overwhelming majority voting in favour of the agreement. But the US Congress has refused to give it their stamp of approval till now, though reports of late suggest that there are some positive movements within the US domestically on this.[18]

Although the agreement is yet to receive congressional approval, the scope and value of this agreement to both these trading partners are not in doubt. Given both the geopolitical and the direct trading interests relating to the Panama Canal Authority, the US is admittedly keen on cementing its strategic ties with this Central American republic. Similarly, for Panama hopes of gaining unilateral trade privileges from the US would help it to compete with the Caribbean nations that have been enjoying liberalized tariff regime for both the US and EU markets under the GSP scheme of trade preferences. It will also enable it to leverage its role as a US trading partner in a region characterized by traditional US opponents. This would then seem to relate to a win-win situation for both the countries; however, the devil in this case lies in the details. An analysis of the text of both the free trade agreement and the single focus agreement on SPS measures would prove the degree of one sidedness, which both these texts exude. Herein we would focus on certain aspects of the free trade agreement and discuss the rationale for establishing a separate agreement on SPS measures.[19]

Amongst one of the innovations, which have been made in this FTA, is the introduction of the special category called "Special Regimes".[20] This is listed under Chapter 3 "national treatment and market access to goods" section, and refers to waiver of custom duties. This section (Article 3.4) creates a legal bar against the revision of the customs waivers adopted under this agreement if it is conditioned on the fulfillment of a performance requirement. The caveat attached to this is that it could be an "explicit or implicit" conditionality, essentially debars any course of action. Under this articles Panama retains the right to maintain existing measures, which are inconsistent, under two conditions. First, that they should be consistent with Article 27.4 of the SCM Agreement. Second, that Panama "may not" maintain such measures after December 31, 2009. It is quite obvious that given such a deadline, Panama will be under immense pressure to withdraw the current regime of customs waiver that are external to this agreement.

The Agreement also contains a specific chapter on Sanitary and Phyto-sanitary Measures. The chapter only affirms the application of the SPS Agreement of the WTO and sets up a consulting and facilitating mechanism in the form of a Committee on Sanitary and Phyto-sanitary measures. Further, the scope of the chapter is wide and, therefore, refers "all" SPS measures that may directly or indirectly affect trade. Amongst the Committee's various functions, it also provides for a forum for prior consensus building on issues and positions in international SPS bodies like the Codex, WTO SPS committee, International Plant Protection Convention amongst others. This is another related trend that is being reflected in such FTAs. Such institutions in reality create a practical imperative to undertake consultations with ones' trading partner on decisions, which should be taken on the basis of national trade priorities. This also highlights the essentially territorial[21] nature of the side effects of such agreements between two unequal trading partners. The agreement puts into place a self-progressing mechanism, which would catalyze closer trade relations between the partners on an ever expanding range of issues – which may not even have featured in the text of the agreement. This is illustrated by the US-Panama FTA in which, although the substantive provisions are limited, the setting up of the Committee and the role and scope determination of the committee has set up a process with a self momentum. On a more pragmatic note, the setting up of a Committee and the lack of any substantive obligations reflects the lack of agreement between Panama and the US at that point of time. It also, therefore, highlighted the need to negotiate a separate agreement on the outstanding SPS issues in the future. The signing of the US-Panama SPS Agreement is a fulfillment of that need.

The latent trigger to the signing of this single focus agreement on SPS measures between the US and Panama has its genesis in the Panama's requirement conducting individual audits by national authorities of the US manufacturing processes, facilities and export shipments that export agricultural products to Panama. The US was keen to ensure that such far-reaching administrative requirements would be done away with and replace them by a wide ranging equivalence measures. The importance of these measures also underlines the need for a separate agreement rather than including such issues within the larger radius of the proposed US-Panama free trade agreement.

The Agreement primarily focuses on three sectors, viz. meat (including but not limited to beef and pork), poultry and its products and processed food (including dairy products). The essential thrust of the Agreement is to recognize and validate the certification provided to the US exports in these sectors by the domestic regulatory authorities without the necessity to undergo the quality controls by the authorities in Panama. The reason behind this is that all these three commodities form the most protected products and almost 40 per cent of the imports from the US. The US in many bilateral forums had contended that process of certification of individual US manufacturing/processing firms by the Panama authorities have been a procedurally cumbersome and an expensive process.[22] Panama has thus in pursuance to the Agreement agreed that it would not require "any additional certification statements to the standard applicable US export certificate, except as provided in this Agreement."[23]

Another important aspect is its focus on laying down procedural time lines. Article 7 of the Agreement specifies that in case of obtaining product registration statement from the Panama Food Safety Authority, the time line have been fixed at "one working day of receiving basic product information about a product". This is indeed unprecedented in terms of the reach of bilateral agreements. Providing for fixed time lines in case of regulatory approvals and specifying automatic issuance product registration certification. These further illustrate the intrusive nature of the Agreement and its impact and influence and fashioning domestic regulatory approvals. Moreover, the Agreement states that, also in cases of animal diseases, viz. avian influence and Newcastle disease, Panama will accept the internal regulatory certificates of the USDA (United States Department of Agriculture) FSIS Export Certificate, as valid. Although this is in conformity with the OIE (World Organization for Animal Health) guidelines, there are very few instances where countries have accepted such measures of equivalence.

In the specific case of importation and sale of beef and beef products, Panama is obligated to "continue to recognize, the US beef grading system, and US beef cuts nomenclature, without review or further action." This is indeed unprecedented, that a bilateral agreement would aim to constrain further action or even review of present domestic measures. This goes much beyond what is meant by equivalence. Since the idea and commitment towards equivalence is an act of recognition of the measures of a trading partner as in conformity (and therefore having the same legal effect as) with domestic regulatory measures. In this case, however, not only is there a legal obligation on Panama to recognize current standards of the US, but of more concern is that censure on future domestic policy changes. Puritans would argue that an international agreement being a legal contract, it is possible to withdraw and rescind from it. However, realistically this is not an option open to Panama, given the historical linkages (both trade and politics) between the two countries.

The above discussion quite clearly elucidates the extensive nature of commitments that Panama has undertaken in the context of SPS measures (with reference to specific goods) with the United States. This is not surprising given the earlier regulatory regime wherein Panama maintained that specific regulatory procedures have been seen to be an expensive exercise and also very time intensive. Nevertheless what is indeed surprising is the nature and scope of this Agreement in terms of mandating detailed and rather sweeping "prior information" and notification commitments preceding any review or change in the regulatory regime by Panama.[24] This will of course facilitate bilateral policymaking in this area; nevertheless the provisions of this Agreement are quite clearly SPS plus in nature and this potentially could constrain the domestic regulatory flexibility of Panama.

What does the above analysis portend for the ongoing India-EU FTA negotiations? There are primarily two issues to which attention could be drawn in this regard. First is that of the SPS standards themselves. As is evident from the analysis of the above two FTAs, India should expect pressure from the EU to agree to extensive harmonization of its legal instruments and institutional infrastructure governing SPS. This would be in terms of accepting the protocols established by EU certification authorities and in the Indian scenario adopting those or similar protocols with the promise of guaranteeing faster and more effective access to the EU markets. As has been witnessed in the US-Panama SPS Agreement, this could either be limited to a few products to begin with but thereafter there will be pressure to extend it to the entire product line being negotiated under the FTA. Second also at the level of regulatory approvals, there may be pressure to streamline the process in terms of specifying strict time lines for gaining such approvals. More importantly, however, it is the review and consultation that are mandated before any change of policy on the regulatory fronts that is of concern. As seen from the earlier discussion, it could be expected that similar responsibilities be specified in the agreement that would make incumbent on India to consult with the EU before undertaking any exercise of review and revision of the current regulatory standard specifically with reference to the SPS measures. This cannot and should not be acceptable to India on grounds that it would be undermine the policy flexibility that is required to design and implement a regime that addresses its domestic priorities.

Institutionally there could be demands made similar to those under the US-Panama FTA. This refers to the setting up of a joint committee to facilitate consultation on SPS measures. Although such an institution can be helpful, however it should be noted that the mandate of such a consultative mechanism needed to be clarified. In the case of an open mandate on engagement there may be pressure to subsequently enlarge the mandate given the new circumstances. Thus, if India does enter into such a mechanism with the EU it would need to be very clear on the purpose, duration and draw a clear mandate for such a mechanism.

The Home Front

In this section we study the domestic institutional and regulatory landscape on food safety in India. This is an important and crucial part of this issue area. Given the fast moving pace of international developments on this issue, it is imperative that our domestic regime is both well entrenched but also flexible enough to address the international demands made on it. In this specific case, a country's negotiating prowess on a specific subject/issue area is largely contingent on the development of its domestic regime and its independent and effective functioning. It is also important at the level of providing crucial national experiential data in equipping negotiators with a knowledge base and multiplicity of choices in designing institutions and regulatory instruments that best reflect the domestic priorities and also fulfill our international obligations as a country. In this regard the following analysis reflects on the institutional aspects of the regulatory bodies dealing with food safety in the country. It also highlights few of the problems of regulatory uncertainty that may be created due to lack of clear mandate of functioning bodies.

The primary aim in highlighting such domestic fissures is to illustrate the highly contested nature of domestic policy making itself on this issue. This further complicates policymaking domestically and could potentially have a negative impact in terms of coordination between the different lead agencies in the international negotiations spanning the CBD (Chazournes. and Thomas *et al.* 2000), WTO and the CODEX committees. Following, therefore, is an overview of the regulatory landscape in India and some of the fissures therein.

In India, the Ministry of Health and Family Welfare (MoHFW) is the oversight authority for food safety. For nearly five decades the Prevention of Food Adulteration Act (PFA), which was enacted in 1954, has been the sole legislation on food safety in India. The primary objective of this legislation was to ensure consumer safety through preventing fraud and deception in food manufacturing and marketing. Since the food safety is a subject that is part of the concurrent list, the enforcement of the Act is the primary responsibility of the State/Union

Territory governments. The role of the MoHFW is advisorial in nature other than few of the statutory functions that it undertakes. The MoHFW is also the designated National Codex Contact Point in India. The National Codex Committee was constituted as an overview agency under which there are twenty-four shadow Committees in concomitance with those in the CODEX that essentially follows the international developments in the committees and helps in preparation of India's submissions.

In August 2006, the entire food safety law in India was overhauled through the enactment of the Food Safety and Standards Act. One of the main features of the enactment is the setting up of the Food Safety and Standards Authority. This provides for a one point regulatory oversight over the entire food chain. This illustrates a shift away, in many ways, from the earlier regulatory ethos of focusing on enforcement mechanisms on the end of the food chain sold in the market to a more preventive approach to risk assessment and reduction of such risk. The primary aim is to deploy regulation at points where it is most effective like in the HACCP classification systems.

Nevertheless despite the enactment of this legislation several delays in notifying the legislation have meant that there is a grey area of regulatory oversight that has been created largely by default. Though the food regimes is to be under the authority of the Food Standards and Safety Authority, the Ministry of Environment and Forests (MoEF) has continued to be in charge of the environmental health impacts of food safety regime specifically with reference to the genetically modified foods regime. This follows through from the parameters set up within the Environmental Protection Act 1986, through the notification setting up of the entire regulatory apparatus of approval of GM crops. Thus since the most important international instrument on GM crops have been developed within the larger framework of the CBD (Convention on Biological Diversity), i.e. the Cartagena Protocol on Biodiversity (Katz, D,2001).

The Cartagena Protocol is essentially an international environmental regime that provides for a system of institutional and regulatory standards that delimits the functioning of the regime. The regime was developed in response to the environmental risks emanating from the international export and import of LMOs (Living Modified Organisms – the name used to refer to the GMOs under the CPB). Thus, the location of the food safety regime within the ministry of environment was partly a reflection of the international institutional arrangements, but also addressed the unique threats that emanate from the development of GM crops within agriculture.

A second aspect, before discussing the implications of such an institutional location, two preliminary points needs to be made. First it is important to keep in mind that though in this section, regime location is construed as crucial facet of regime architecture, it does not in any way deny the numerous influences both domestic and international in determining regime development and functionalities. Second, one of the inherent assumptions of this facet of examination is that there are certain forms and processes of regime architecture which the location of the Ministry of Environment privileges over others and that has certain implications of the nature and operation of the food safety regime itself and most importantly for its development.[25] The GM regime exemplifies the importance of this contextual dynamics of regime location. The Indian environmental regime governing GM crops has a long history. India was one of the early subscribers to a specialized GM environmental governance regime. The notification on GM regulation was brought into place as early as in 1989. Interestingly this was before any known commercial plans to invest in GM research were unveiled in India. Such a precautionary posturing could perhaps be attributed to the domestic judicial drive that was witnessed during the late eighties through the nineties on environmental issues and the executive response to it. This period also saw the overhauling of the environmental regime in form of the enactment of the Environmental Protection Act, 1986.

However, thereafter especially through the late nineties, the techno-optimism that characterized the investment and development of biotechnology saw a clear posturing of the government to go slow on regulations. This was also evidenced by the clear lack of regulatory control in terms of institutional capacities that were pre-requisites for the legislative oversight. Another proof of the government stand was also the sudden change of government policy by proceeding with an executive order (notification) in mid-August last year.[26] The notification essentially used an exception clause enabling the MoEF to provide for the non-application of the notification if it so warranted. The notification does not provide for specific conditions under which the ministry can take such a position and therefore provides for wide discretionary powers to the MoEF. This *per se* is not legally problematic but in case of abuse of such discretion in clear violation of the legislative intent underlying the enactment of the GM notification, this may be legally challenged. The August notification of the MoEF essentially provides for a blanket exemption of GM regulatory oversight on the imported GM food. This is surprising given that there has been no overall policy change in the government on such issues. Further, there has been a significant rise in the import of GM food especially through the rise of retailed vegetable shopping chains. Also this kind of a stand is very much opposite to the government of India's international stand on eco-labelling of GM food at the CODEX. Since then there has been a case filed against this order in the Supreme Court, and the Ministry has put the notification in abeyance for a period of six months pending further direction from the Food Safety and Standards Authority under the Ministry of Health and Family Welfare.[27]

The above is just one of the various illustrations that characterize the conflictual and highly contesting nature of the food safety administration in the country. Thus, it would be naïve to imagine that even having a consolidated authority would iron out all the problems, specifically because in the context of the environmental health aspects of GM food would require the expertise of the MoEF. In that sense it is critical that any such step would have to be supported by a clear plan of inter-ministerial action and support structure that would enable effective oversight of food safety in India. Such inter-ministerial deliberation and action is also critical in providing for a formative strategy in dealing with international negotiations at different forums on food safety. Thus, other than the MoEF, the MoHFW, it is the Ministry of Commerce which would have to be involved in the coordination of such responses, given that it is in overall charge of the international trade negotiations both at the bilateral level and at the multilateral institutional level of the WTO.

Concluding Remarks

Discussion in the above sections highlights the contested nature of the sites of international decision-making on food safety. This contestation is not necessarily a negative issue, since it also illustrates the diverse nature of the actors that are involved and, therefore, have to be accommodated within the different forums (Anderson and Nielsen, 2004). However, what is quite apparent are the increasing demands that emanate from such forums on the developing countries to participate and influence standard setting related decision-making therein. What is of concern is the privileging of bilateral forums over multilateral ones in the drive for harmonization on food safety regimes. Given the inherently unequal nature of these forums, it creates tendencies for inordinate influence of the larger trading partner (Barton, 1996). This is quite apparent from two instances of such bilateral agreement analyzed in this paper.

In this context one would need to underline a couple of caveats. First, food safety regulation within the trade regime would take centerpiece given the increasing use of non-tariff barriers by countries while regulating trade. Second, this would automatically raise the profile of bodies like CODEX in terms of authorizing regulations that lay down the basis of food safety regulations that are recognized as "legitimate" within the framework of the WTO (Bentley, 2001). Third, this creates institutional pressures within the CODEX to respond to the demands of the variety of actors that are interested in participating in the deliberations. These issues of legitimacy would have to be addressed both within the CODEX and/or through the other forums like the dispute settlement or through the various committees of the WTO wherein procedural requirements could be debated and adopted in order to guide decision-making within the CODEX. It is also important to focus on bilateral developments and resist pressures from larger trading partners in adopting standards that clearly go beyond those mandates under the SPS Agreement. Herein it is important to reiterate that multilateral forums like the CODEX or the WTO remain ideal institutionally to provide for negotiations on this issue, given the nature and scope of the food safety regulation.

At the national level, the setting up of the Food Safety and Standards Authority is a critical institutional innovation in the context of the food safety regime. Given the institutional convergence that is required between the MoEF, MoHFW and the Ministry of Commerce, having a one point institutional mechanism is required. Further, food safety within the context of international negotiations is shared across international negotiating platforms like that of the CBD, WTO and the CODEX. Thus, it is important that there is sustained and regular interactions that are institutionalized through the oversight of the Food Safety and Standards Authority.

Endnotes

[1] "It is widely recognized that SPS measures can act to impede trade in agricultural and food products." Impact of SPS Measures on Developing Country Export of Agricultural and Food products, World Bank, 1999.

[2] There are currently 167 members and 149 NGOs have observer status.

[3] See Joint FAO/WHO Food Standards Programme, General Principles of Codex Alimentarius, in Codex Alimentarius Commission Procedural Manual 30 (14th ed. 2004).

[4] See Michael Livermore, Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation and the Codex Alimentarius, 81, N.Y.U. Law Review, 774 (2006).

[5] Under the SPS Agreement, members "shall base their SPS measures on international standards"; Article 3.1. Under the TBT Agreement, members "shall use them or the relevant parts of them, as a basis for their technical regulations"; Article 2.4.

[6] Annex A to the SPS Agreement, Section 3(a), defines international standards relating to food safety.

[7] Embassy of India, International Harmonization of SPS Standards, Paper submitted by India in the WTO Committee on SPS Measures; http://www.indianembassy.org/policy/WTO/wto_india/harmonise_sps.htm , paper last accessed on 12th December 07. Also Lori M. Wallach, Accountable Governance in the Era of Globalization: The WTO, NAFTA and International Harmonization of Standards, 50 U. KAN. L. REV, 826 (2002).

[8] W. Bruce Triaill. et al, Report of the Evaluation of the Codex Alimentarius and other FAO and WHO Food Standards Work, FAO and WHO, November 2002.

[9] Procedural Manual of the Codex Alimentarius Commission. 16th Edition. FAO, Rome.

[10] The Codex Decision making Process and the Extent to Which Other Factors are taken into Account: This includes both the statement of the Criteria in the first statement in 1995 and thereafter in second statement of the principle in 2001.

[11] See also, Cassese S, Shripms, Turtiles and Procedure: Global Standards for National Administrations 15 (InternationalmLaw and Justice, Global Administrative Law Series, Working Paper No. 2004/4, 2004).

[12] Livermore Michael, Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius, NYU Law Review, May 2006.

[13] Supra Note 11.

[14] Supra.

[15] Appellate Body Report, European Communities – Trade Description of Sardines, WT/DS231/AB/R, (September 2002).

[16] See also, Cassese S, Shripms, Turtiles and Procedure: Global Standards for National Administrations 15(InternationalmLaw and Justice, Global Administrative Law Series, Working Paper No. 2004/4, 2004).

[17] United States – Panama Agreement Regarding Certain Sanitary and Phytosanitary Measures and Technical Standards Affecting Trade in Agricultural Products. December 20, 2006.

[18] See http://www.bilaterals.org/article.php3?id_article=13099 accessed 12/9/08

[19] United States-Panama Agreement Regarding Certain Sanitary and Phytosanitary Measures and Technical Standards Affecting Trade in Agricultural Products. December 22, 2006

[20] See Section C of Chapter Three, "National Treatment and Market Access for Goods", US-Panama Trade Promotion Agreement

[21] In this context the use of the word "territorial" is implied to mean the unclear nature of territorial boundary and the essential national urge to extend them through annexation of territory.

[22] United States Trade Representative. 2007 National Trade Estimate Report on Foreign Trade Barriers. Washington, D.C. March 2007. p. 452.

[23] Supra Note 15

[24] Supra 11.

[25] See more generally for similar assumptions; Post Diahanna; Standards and Regulatory Capitalism:The Diffusion of Food Safety Standards in Developing Countries, The Annals of the American Academy of Political and Social Science; 598; 168, 2005.

[26] MioEF Notification number S O 1519E.

[27] Notification S.O. 411E 25 February 2008.

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The Cost of Research and Development for Producing a Transgenic Crop and Its Biosafety Regulation Compliance in Indonesia

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Abstract: Since the last decade crop improvement using genetic engineering tools is one of the alternative approaches to increase and stabilise agricultural production in the world. However, producing a transgenic plant is a long and expensive process. Even after it led to the successful development of a plant with a desired trait, the transgene has to be followed up by a series of risk assessment stages required by the national biosafety commission. A risk assessment regulation process is required to assure the safety of food and feed and the environment and this latter activity is not costless. The objective of this study is to obtain the cost for research and development of selected transgenic crops engineered in Indonesia. In addition, we also investigated the cost of complying with the biosafety regulation. The result of our survey shows that it took 4-8 years to engineer a transgenic plant. Two of the samples' activities were started from gene isolation, and the rest were started from tissue culture and plant transformation using foreign genes. The R&D cost needed for each activity was around 1.3 billions IDR to 3.1 billions IDR (with Present Value of money (PV) equal to 2.3 billions IDR to 7.1 billions IDR). Those amounts were equivalent to US$154 thousands to US$522 thousands (US$274 thousands to 1.4 million PV). To comply with the regulation requirements for Bt-cotton, a multinational enterprise in Indonesia had paid around 919 millions IDR (974 millions IDR PV) equivalent to US$ 93 thousands (99 thousands US$ PV). These biosafety costs excluded the food/feed safety costs. Our survey also indicated that from 31 plant transformation activities, 16 are still on going, while the rest were either suspended or terminated. Of all 16 activities only two preceded into the regulation phase. Because producing a transgenic plant and complying with regulatory approval for commercial release are expensive and a long

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process, it is wise to set the research priorities based upon the country capacity and need. Research priorities should also based upon the estimation of the risk and benefit of all activities or stages. This includes the estimation of the fund needed starting from the initial activity to the last (release of the new variety).

Keywords: Biosafety regulations, Cost of biosafety, R&D, Transgenic crops, Risk assessment, Socio-economic assessment.

Background

Despite the ongoing debates between the opponents and proponents of transgenic plants, there is a substantial increase in cultivated area globally for transgenic crops. During the eight-year period 1996 to 2003, global areas increased forty fold from 1.7 million ha in 1996 to 67.7 million ha in 2003.[1] In 2005, the global approved GM crop was 90 million ha grown by 8.5 million farmers in 21 countries (10 industrial and 11 developing countries).[2]

Construction of transgenic plants was initiated in Indonesia in the mid 1990s. By then, there had been an increase in the number of Government and private institutions that performed research on transgenic plants. Along with the increasing number of institutions, the target plants and introduced traits have also become more numerous and have diversified.[3]

Due to the existing controversy on the benefits and risks of transgenic plants and their derivative products, the Indonesian government recognised the need for application of the technology with the "cautiousness" principle. This is reflected in various government regulations and decrees issued either by the President or by related Ministers. In 1996, the Government issued the first Law on transgenic plant which called "Undang-undang Pangan" no. 7/ 1996. In 1997, the Minister of Agriculture issued an SK No. 856Kpts/ HK330/9/1997, a Ministerial Decree to regulate the biosafety of agricultural biotechnology products. This new Law/Decree was later revised in 1999 in a Joint Decree of the four Cabinet Ministers. Aside from biosafety, the new Decree had also made additional regulations on food safety. The Biosafety Commission was formed in 1997. These regulations on transgenic plants are continue under revision, and the Government Regulation No. 21/2005 (PP 21/2005) was the latest decree on this issue. PP 21/2005 was a modification of the joint-decree previously issued by the four Cabinet Ministers to accommodate the implementation of Cartagena Protocol, which was ratified by the Indonesian government in 2004.

PP21/2005 was issued to attain environmental safety, safety of food and/or feedstock produced by genetic engineering and their respective uses in farming, fisheries, forestry, industries, environment and public health. The approach used in assessing the risk is based on the principle of cautiousness, founded on solid scientific methods and also includes religious, ethical, socio-cultural, and aesthetical value considerations. In order to implement this government regulation, a system guideline is required to determine which institutions need to be involved, which procedures/protocols need to be followed and a clear legal structure. All of these require sufficient funding, whether it is for acquisition, operation, or monitoring. The funding would be required for research in laboratories, greenhouses, and field work for the purpose of gathering data requested by the Biosafety Committee (BC) through its Technical Team (Biosafety Technical Team or BTT) and their operational budgets, and other indirect costs required for fulfilling the aforementioned guidelines.

In some countries that have approved transgenic plants for commercial release, the total cost of releasing the transgenic plant commercially has been compiled and analysed.[4] One such example is the release of a mustard plant variety (a close relative of canola) in India, which has been transformed with a gene that has been used to transform canola in Canada and the USA. Since such a plant has never been released anywhere in the world, its producer (Bayer Inc) had to spend 3-4 million US $ for food safety tests, which were carried out in the USA and Europe. Another 1-1.5 million US $ had to be paid for research on the environmental risk analysis performed in India. Bayer had started this process in the early 1990s, but determined to stop its attempt to release transgenic mustard in India on 2003. This illustrates how costly it is to conform to and follow the regulations for a commercial release, even when the proponent decided not to continue trying to commercialise hybrid mustard in India at the end. Such high expenses clearly bear some consequences:

1. Farmers cannot utilise seeds of transgenic plants on their farmlands since their approvals are cancelled or withdrawn.
2. The high cost associated with the approval process would be passed on to farmers, causing seed price to increase beyond their reach.

Another aspect that needs to be considered is whether such expensive approval cost is within the reach of the public research institutions and universities or whether it is cost economic for one of their researchers to release transgenic products commercially. Could this mean attempts in constructing transgenic plants that often took years to complete and significant investments would reach a stalemate when the researchers seek regulatory approval? Many researchers in public institutions as a consequence would not consider conducting research on creating transgenic plants. So that society will lose the benefit of transgenic-technology to improve the common welfare.

This study attempts to calculate and analyse the expense for several research projects in four Indonesian government-funded institutions for the construction of transgenic plants and other experiments that need to be carried out to comply with regulatory requirements for commercial release of those plants. For comparison, similar expenses in the commercial release of a multinational company are also calculated and analysed.

Methodology

This study chose the sample institutions based on the following criteria: (i) institutions that carried out constructions of transgenic plants where the resulting plant is already at the stage of application for release within the next 2-3 years with the regulatory body; (ii) institutions that have obtained release approval; and (iii) institutions with a mandate to assess food and biological safety for commercial releases. The selected institutions are listed in Table 1.

Data were collected by using a structured questionnaire in interviewing subjects. The questionnaire was a modification of a standard questionnaire created by Dr Jose Falck-Zepeda for a similar study in several developing countries. In general, the data sought in the questionnaire for those institutions performing transgenic plant construction was as follows: (i) description of the institutions; (ii) type of transgenic plant research; (iii) direct and indirect costs for constructing the transgenic plants; (iv) description of the stages of transgenic research; and (v) facilities and equipments used for the construction of the transgenic plants. The data scope of the questionnaire for institutions already obtaining approval for release was as follows: (i) description of the institutions; (ii) type and research stages of the transgenic plants subjected to approval; and (iii) direct costs of research/assessment on the transgenic plants that would be released or had already been released. The data scope of the questionnaire for BFSTT (Biosafety and Food Safety Technical Team) included the operational costs of BFSTT and the number and status of applications evaluated.

Table 1: Sample (Institution) Selected for the Study

No.	Institution	Activity	Year of activity initiation and entering regulation phase
1	Biotechnology Research Center, Indonesian Institute for Science, Cibinong	Genetic engineering of rice plant for rice stemborer resistance using cry 1A gene	1996 (starting with rice tissue culture system coincided with plant transformation and etc).
2	Department Agronomy, Bogor Agriculture University, Bogor	Genetic engineering of potato plant resistance to fungi/nematode using chitanase gene	1994 (starting with gene isolation, then plant transformation and etc.. the project was temporarily suspended for a year)
3	Department of Plant Pests and Diseases, Udayana Univeristy, Denpasar	Genetic engineering of citrus plant for virus (CVPD) resistance.	1997/98 (starting with gene isolation, then plant transformation etc.)
4.	PTPN XI, Surabaya	Genetic engineering of sugarcane plant for drought tolerance using betA gene	1999 (starting with sugarcane tissue culture system, then plant transformation, etc.)
5	PT Monsanto (PT Monagro)	Application for commercial release of Bt-cotton and Roundup ready Corn	Application for commercial release of Bt-cotton (Bollgard) was in 1998 and RR corn in 2002
6.	Others (Biosafety and Food Safety Technical Team' coordinator, members, supporting staff, and related persons in related institutions)	Regulations, law, decree regarding biosafety and food safety of transgenic crops, and activity of the technical team including conducting meeting for data evaluation, number of persons attending a meeting, funding source to run the office, etc.	

Estimation of the cost of research in constructing transgenic plants was split into direct costs and indirect costs. Direct costs are expenses directly spent on research projects. This would include the costs of materials, wages, travel budget, and stationeries. Indirect costs are expenses not directly related to the research project, such as salaries (20 per cent of total wages), electricity, water, gas, equipment maintenance, and depreciation values of research equipments. Since payments for electricity, water, and gas bills is normally made for the whole institution, the actual cost for this is estimated according to the kind of equipment used in the project and the size of the lab carrying out transgenic projects. Data on indirect costs is also normally only available for the most recent year, while the construction of transgenic plants will already started several years before. Thus, the indirect costs for the previous years were calculated using a discount factor from the available data.

If the project is not handled exclusively by the sampled institutions, then the cost data would be obtained by cross-checking with the other institution participating in the said project.

The following table lists the assumptions used in calculating the cost of research and evaluation of transgenic plants:

Assumption we used in calculating the calculating cost of research and development and biosafety regulatory is as follows:

Variables	Assumed Values
Interest rate	18%
New inventory laboratory equipments	Estimated of equipment' value
Maintenance of equipment	1% of equipment' value
Depreciation	5% of equipment' value
Salary	20% of salary

To make the data more comparable with data from other countries, the resulting calculations were converted from the Indonesian currency (IDR) to dollar. In order to obtain the cost of research and evaluation for the current year, we calculate the present value using the following formula:

$PV = A^*(1 + r)^n$

Where :

A : Cost in year (current – n)
r : interest rate
n : number of years.

As previously mentioned, information on indirect costs normally is available only for the most recent year; therefore the cost for the previous years was calculated using a discount factor (DF) following the formula below:

$DF = A^{*}(1 + r)^{-n}$

Where :

A : Cost at a certain year
r : interest rate
n : number of years.

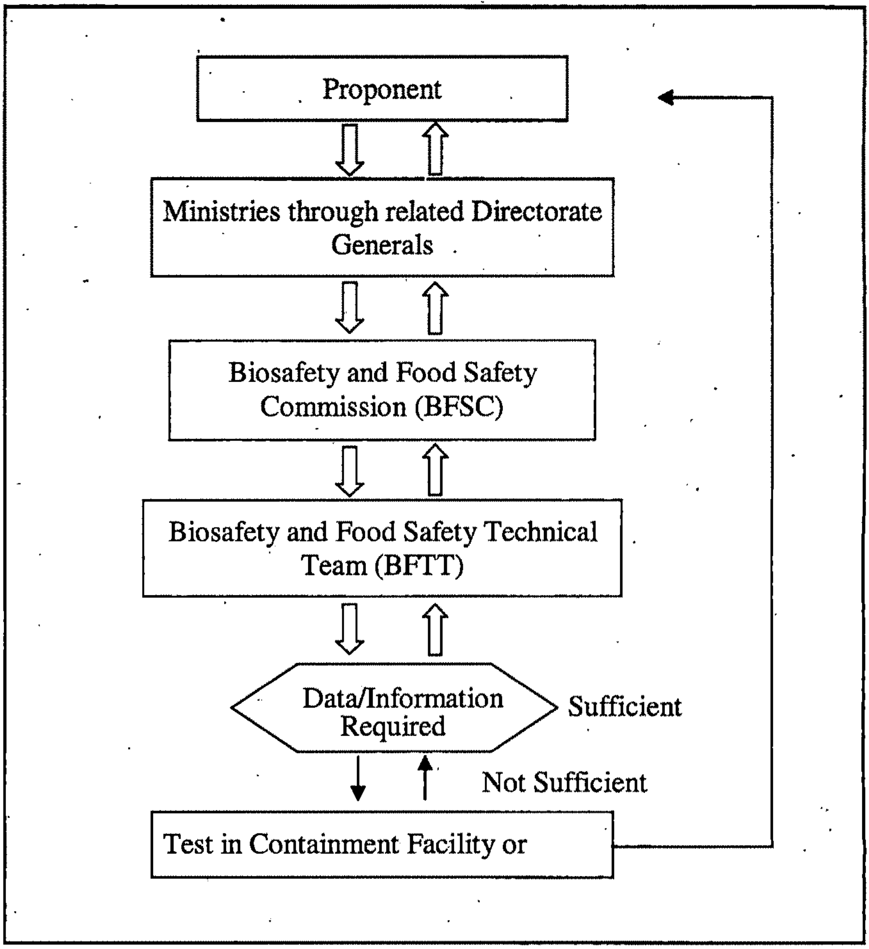
The information we collected from institutions that gained approval for commercial release (Monsanto Inc.) only covered the direct costs, since most research works were subcontracted to the various institutions. Information we obtain from Monsanto are only restricted to the research and other activities that were carried out in Indonesia during their field trials in compliance with the regulation for gaining approval in this country. Meanwhile, we had not successfully obtained the information on costs spent to do research and other activities performed outside of Indonesia (mostly in the USA).

Results and Discussion

I. Indonesian regulatory system for the biosafety of genetically engineered products

During the course of this study, Indonesia still used the guidelines set by the joint decree of Ministers known as SKB4M (SK Menteri No. 998.1/Kpts/OT.210/9/99; 790.a/Kpts-IX/1999;1145A/MENKES/SKB/IX/ and 1999 015A/NmenegPHOR/09/1999) for assessing the biosafety of genetically-engineered products. The decree set the procedure for analysing the biosafety and food safety of GM products to be released commercially in Indonesia. In addition, the appendix of the decree specified the membership of the Indonesian Biosafety and Food Safety Commission (BFSC). Article 39 stated that BFSC would be assisted by the Biosafety and Food Safety Technical Team (BFSTT), whose membership would be determined afterwards. The membership was later enacted by another joint Ministerial decree, SK No. LB.010.59.1.2000, 77/Kpts/9/2000 and KS.01.01.03380. The head, secretary, and members of the BFSTT are the Executives from the associated Ministries, Director Generals, Head of Directorates, Head of Research Centers, Head of PAU IPB, President of Biotechnological Association and Consortium, Head of Kehati Foundation (an NGO Representative), Head of Indonesian Consumer's Foundation, and Head of Indonesian Farmers Association, which added up to 21 members. The head and secretary of the BFSTT are *ex-officio*, and its membership consists of senior researchers from research institutions and universities from various disciplines. The membership is divided into five groups, namely: The Plant Group (11 members), Animal Group (7 members), Fishery Group (5 members), Microbial Group (11 members), and Food Group (17 members). The assessment procedures are summarised in Figure 1.

Figure 1: Scheme/Procedure for Risk Assessment based on *SKB4M*


Proponent
Ministries through related Directorate Generals
Biosafety and Food Safety Commission (BFSC)
Biosafety and Food Safety Technical Team (BFTT)
Data/Information Required
Sufficient
Not Sufficient
Test in Containment Facility or

Until this paper was written, the BFSC had only met several times to decide the status of the commercial release of the released Bt cotton from Monsanto. Most day-to-day activities were carried out by the BFSTT. The operational costs of the BFSTT were obtained from the proponent/applicants. Table 2 lists the BFSTT operational costs from 1998 to 2004.

Table 2: Operational Cost of BFSTT Activities

Year	Total Cost (million IDR)	Present Value of Cost (PV 2005, million IDR)	Present Value of Cost (PV 2005, thousand US$)
1998	50	159	16.1
1999	11.5	31	3.9
2000	10	23	2.9
2001	38	74	7.2
2002	104	171	18.4
2003	32	45	5.2
2004	12.5	15	1.6

The operational cost mostly covers the expenses for conducting meetings to assess the collected data, making decisions on the safety of certain genetically-engineered products, and creating guidelines for the food safety. The costs may differ each year, since they depend on the number of applications submitted to the team. As BFSTT also consists of different groups, the attendance level in meetings can also vary, depending on the case being examined. Table 3 lists the attendance level of members and their supporting staff.

Table 3: The Frequencies of BFSTT Meeting based on the Number of Attending Members*

No of members attending	No of meeting
5 - 10	5 meetings
11 - 15	9 meetings
16 - 20	9 meetings
21 - 25	4 meetings
25 - 30	1 meeting

*(n = 28 meets)

On an average, BFSTT meetings are held eight times per year. Most of the time, the meeting is attended by one coordinator and one leader, ten researchers, and three supporting staff. The cost of each meeting and the annual budget can be seen in Table 4.

Table 4: The Average Cost of BFSTT Meeting to Evaluate Dossier and/or Additional Required Data

Items	Direct cost per meeting		Indirect cost (10% of one month salary) per meeting		Total cost per meeting		Total cost of meeting per year (8x meets)	
	IDR	US$	IDR	US$	IDR	US$	IDR	US$
2 managerial honorarium	1,000,000	102.94	600,000	61.77				
11 researcher honorarium	3,300,000	339.72	2,750,000	283.10				
3 supporting staffs honorarium	600,000	61.77	450,000	46.32				
Meeting expenses	1,200,000	123.53						
Total	6,100,000	627.96	3,800,000	391.19	9,900,000,-	1,019.15	79,200,000,-	8,153.18

Although the BFSTT was established on 2000, research and assessments on the biosafety have been conducted since 1998. Four applications from Monsanto were submitted that year. By then, the activity was limited to biosafety assessment in a containment facility located in ICABIOGRAD. A small percentage of the budget was used to hold meetings to assess the biosafety issues and recommendations to be made. In total, there were five applications submitted in 1998, one application in 1999, one application in 2000, five applications in 2002, and two applications in 2003. Among these, only one application, Bt Cotton (Bollgard from Monsanto), gained approval for limited field releases in seven districts of the province of South Sulawesi. Seven applicants have been approved and recommended by the BFSTT as "safe for environment", but are yet to receive formal approval from the responsible Directorate Generals/Ministers for their commercial releases. The costs spent by each applicant for the BFSTT approval ranged from IDR 9 million (PV IDR 28 million) to IDR 51 million (PV IDR 83 million). This is more clearly illustrated in Table 5.

II. Recent Status of Research and Developments on the Construction of Transgenic Plants Activities in Indonesia

The purpose of this study is also to upgrade information on transgenic research in Indonesia so that the results published by the previous studies done on this topic may be updated.[5] The results are shown in Table 6.

Between 1996 and 2005, there were 31 transgenic plant construction activities, which were carried out on 20 different commodities (food crops, estate crops, horticultures, and forestry) involving 23 different introduced traits. The institutions working on those projects were Agency for Agricultural Research and Development (Ministry of Agriculture), Center for Biotechnology Research, Indonesian Institute of Science (State Ministry of Research and Technology), universities, several government-owned corporations (PTPN), and private corporations. Out of those 31 activities, only 16 were still active, while others were either temporarily suspended or terminated due to several reasons like funding termination, lack of progress, and alteration of priorities. Only two out these 16 activities ever made it to the regulatory process for approval.

Table 5: Budget for Environmental Risk Assessment Activities (million IDR)

Proponent	Commodity	Biosafety status	Experiment containment facility (FUT) at ICABIOGRAD	Dossier biosafety	Dossier food safety	Evaluation for FUT/ LUT data	Registration	Total	PV 2005 (x 1 million IDR)	PV 2005 (x 1,000 US$)
Monsanto	Corn-RR1 and corn RR-2	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	Bt-cotton	Safe for environment	8.0 (1998)			3.5 (1998)		11.5 (1998)	36.63	3.71
Monsanto	RR-cotton	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	RR-soybean	Safe for environment	5.5 (1998)			3.5 (1998)		9 (1998)	28.67	2.90
Monsanto	Bt-corn Mon-810	Safe for environment	8.0 (1998)			3.5 (1998)		11.5 (1998)	36.63	3.71
Pioneer	Bt-corn *cry*1Ab	pending	8.0 (1999)			3.5 (1999)		11.5 (1999)	31.04	3.98
Rosindo	Ronozyme	Safe for environment		10 (2000)				10 (2002)	22.88	2.47
Monsanto	Bt/RR cotton	Only for experiments	11.5 (2001)			6.5 (2001)		18 (2001)	34.90	3.40
Novartis	Bt-corn and Pacha-corn	Withdrawn by proponent		20 (2001)				20 (2001)	38.78	3.78
Monsanto	RR-corn NK603	Waiting for biosafety and food safety status	9.2 (2002)	10 (2002)	10 (2002)	21.8 (2002)		51.0 (2002)	83.79	9.05

Table 5 continued

Table 5 continued

Proponent	Commodity	Biosafety status	Experiment containment facility (FUT) at ICABIOGRAD	Dossier biosafety	Dossier food safety	Evaluation for FUT/ LUT data	Registration	Total	PV 2005 (x 1 million IDR)	PV 2005 (x 1,000 US$)
Monsanto	RR-corn GA21	Safe for environment			10(2002)			10 (2002)	16.43	1.77
Monsanto	RR-soybean	Safe for environment			10 (2002)			10 (2002)	16.43	1.77
Dupont	Bt-corn *cry*1Ab	Waiting for the status		10 (2002)				10 (2002)	16.43	1.77
IIS (LIPI)	Bt-rice for permit to run confined field trials					6 (2002)		6 (2002)	9.86	1.06
PTPN XI	Sugarcane bet-A for permit to run confined field trial		8 (2003)			4 (2003)		12 (2003)	16.71	1.95
PT Behn Meyer	Finase P and L	Safe for environment		20 (2003)				20 (2003	27.85	3.25
Dupont	Bt-corn *cry*1F	Only for registration					12.5 (2004)	12.5 (2004)	14.75	1.64

(....) : Number in parenthesis indicates year of activity.
FUT = containment facility at the ICABIOGRAD; LUT = confined field trial legally permitted by the BFSTT.

Table 6: The Status of GM Crop Researches in Indonesia (2005)

Crop	Lead Institution	Target trait	Gene	Status
Rice	ICABIOGRAD	Resistance to rice stem borer	*cry*	Plasmid reconstruction, plant transformation (on-going)
	RCB- IIS	Resistance to stem borer	*cry*	Limited field trials for plant phenotype (morphological performance, level of plant resistance to major rice pests and diseases) and impact on non-target spesies(on-going)
	RCB- IIS	Resistance to blast	antc, psmp	Bioassay in greenhouse (containment facility)(on-going)
	RCB- IIS	Resistance to blast	chitinase	Greenhouse (suspended)
	RCB-IIS	Drought tolerance	Homeobox	Bioassay in green-house (containment facility) (on-going)
	RCB-IIS	Brown planthopper resistance	Snowdrop Lectin	Green-house (suspended)
Maize	ICABIOGRAD	Stem borer resistance	*cry*	Green-house (suspended)
	ICABIOGRAD	Stem borer resistance	Pin II	Green-house (suspended)
Sweetpotato	ICABIOGRAD	Insect resistance (sweet potato weevil)	Pin II	Green-house (suspended)
	ICABIOGRAD	Viral resistance	Coat protein	Green-house (suspended)
Soybean	ICABIOGRAD	Podborer resistance	Pin II	Green-house (suspended)
	ICABIOGRAD	Podborer resistance	*cry*	Green-house (suspended)
Papaya	ICABIOGRAD	Delay ripening	Antisense ACC oxidase	Screen house, phenotype study(on-going)
Cacao	BRUEC-semi private	Podborer resistance	*cry*	*In-vitro* planlet (suspended)
Coffee	BRUEC	Fungi (rust) tolerance	chitinase	*In-vitro* planlet (suspended)
Sugarcane	PTPXI-ISRI	Drought tolerance	Choline dehydro genase (bet A)	Limited filed trials for morphological characteristic, and sugar content (on-going)
	BAU-public	Phosphor absorption efficiency	Phytase	*In-vitro* planlet (on-going)

Table 6 continued

Table 6 continued

Crop	**Lead Institution**	**Target trait**	**Gene**	**Status**
Chili pepper	BAU	Resistance potato virus Y	Coat protein	Green-house (Terminated)
Groundnut	ICABIOGRAD	Virus PStV resistance	Coat protein	Green-house facility (suspended)
	BAU	Virus PStV resistance	Coat protein	Green-house facility (suspended)
Potato	BAU	Fungal/nematode resistance	chitinase	Green-house facility(on-going)
	BAU	Potato virus P and Y	Coat protein	Greenhouse(terminated)
	ICABIOGRAD-IVRI-public	Late blight(*Phytoptora infestan*)	RB gene	Plant transformation (on-going)
Tomato	ICABIOGRAD-IVRI	Tomato yellow curl virus	Coat protein	Green-house(on-going)
	ICABIOGRAD-IVRI	Cucumber mosaic virus	Coat protein	Green-house(on-going)
Teak	Bandung Institute for Technology - public	Prolong vegetative stage	Leafy gene	*In-vitro* plantlet (suspended)
Orchid	Gajah Mada University-public	Improved quality	Knox gene	*In-vitro* plantlet(on-going)
Citrus	Udayana University-public	CPVD resistance	Newly explored	Green-house facility (suspended)
Eucalyptus	PT Ararabadi-Indah Kiat- Pulp/forestry private company	Disease resistance	Un-known (confidential)	Green-house(on-going)
Cabbage	Airlangga University-Gajah Mada University-public	Disease resistance	Glucanase	*In-vitro* plantlet (terminated)
Cassava	RCB- IIS	Free amylose	Blenching enzyme (be-1 and be-2)	Green-house(on-going)
Acasia	RCB- IIS	Lignin content	4CL	Gene isolation, plasmid construction, In-vitro plantlet(on-going)
Sengon (*Paraserianthes falcataria*)	RCB- IIS	High growth	Xylolase and Xylo-glucanase	Green-house(on-going)

III. R&D Transgenic Plant Construction Activities in Indonesia

III.1. Construction of Transgenic Potatoes Resistant to Fungi/ Nematodes at the Department of Agronomy, Bogor Agricultural University (BAU)

The research on transgenic potatoes resistant to fungi/nematodes was a collaboration between researchers from the Department of Agronomy (Faculty of Agriculture, Bogor Agricultural University), Department of Biology (Faculty of Mathematics and Science, Bogor Agricultural University), and Plant Research International (PRI) in Wageningen, The Netherlands.

The project began in 1994 with isolation of the chitinase gene from *Aeromonas caviea* strain W57b, which was obtained from a soil sample from the Island of Bangka. The gene isolation was performed by Dr. Suwanto et al at the Department of Biology, Bogor Agricultural University, in a three year project funded by RUT. The next phase was the construction of plasmids, vectors, and potato transformations, which was completed in 1998-1999 by Dr. Armini Wiendi for her PhD study in a sandwich programme between Bogor Agricultural University and PRI. The resulting material was transported to Indonesia for further research. The transformants were subsequently regenerated and acclimatised for growth in a greenhouse. More studies were performed at BAU to confirm the gene integration, and the transgene function was also confirmed using enzymatic assays. Greenhouse testing was carried out at Pasir Sarongge between 2002 and 2004 to assess the phenotype and resistance to pests and diseases. Overall, this project was funded by RUT grants for six years (two periods of 3 year grant) and PRI (in the form of scientific training at PRI) for nine months. The details of the project expenditure are listed in Table 7.

It can be seen that during the eight years that the project was carried out, a total of IDR 1.5 billion (PV 2004 IDR 2.5 billion), which was equivalent to US $ 317,000 (PV 2004 US $ 650,000), has been allocated for it. However, this project was subsequently stopped or downsized due to a lack of funding.

The resulting product has not been registered for approval in accordance with the joint ministerial decree, but some preliminary studies have been carried out to obtain some data that would be required for release approval. One example was the greenhouse testing on an

Table 7: Actual and Present Value of Cost of R&D of Potato Resistance to Fungi/Nematode at BAU

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1994	Gene Isolation	139,586	415,472	64.504	191.99
1995	Gene Isolation	146,712	365,259	65.119	162.12
1996	Gene Isolation	155,120	325,076	66.093	138.51
1997/1998	Plasmid/vector Construction *	133,835	236,624	26.039	36.89
1999/2000	Plasmid/vector Construction, plant transformation, and analysis insert gene *	148,944	294,969	18.661	29.87
2001	*In vitro* enzymatic analysis	111,922	139,855	11.884	17.12
2002	Plant phenotype (green house)	185,866	216,865	19.998	25.41
2003	Plant phenotype, plant resistance to *Fusarium* and *Alternaria* (green house)	215,102	231,122	22.774	22.51
2004	Plant phenotype, plant resistance to *Fusarium* and *Alternaria* (green house)	244,800	244,800	22.504	26.43
	Total	**1,481,887**	**2,470,043**	**317.58**	**650.86**

Notes: - Present Value (PV) for 2004, with interest rate of 18%
- Not include food safety assessment/analysis
- *Experiments were conducted at PRI, Wageningen, the Netherland (the materials and equips were subsidised)

experimental plot owned by Bogor Agricultural University at Pasir Sarongge to study the phenotype of the plants. According to the researcher in charge, this is necessary since potatoes are normally planted at high altitudes, while containment facilities for transgenic plants that are available in Bogor and Cibinong were both located at low altitudes, which made them unsuitable for growing potatoes. Also, the team responsible for the evaluation of experiment at the containment facility was still dominated by food crop specialists.

III.2 Construction of Transgenic Citrus Resistant to CPVD at the Department of Plant Pathology, Faculty of Agriculture, Udayana University (Denpasar)

The development of Citrus resistant to CPVD began in 1997 with the isolation of a resistance gene toward CPVD from *Triphacia aurantolia* (jeruk kit kit), a resistant wild citrus species. The gene was later introduced into some local citrus varieties called jeruk keprok by Kintamani and Soe, using *in planta* agrobacterium transformation method.[6] This project was funded by RUT for six years (two periods of three year grant) and JSPS for two years. Part of the research on gene isolation, sequencing, and plasmid construction was performed in Japan (University of Nagoya, Japan). The part of the project carried out in Japan was largely subsidised by the University of Nagoya, and utilised equipments available at the university laboratories. The total funds consumed by the project are summarised in Table 8.

It can be seen that this eight year project in total has used IDR 3.1 billion (PV 2004 IDR 5.6 billion) of research funds, or equal to US $ 370,000 (PV 2004 US $ 641,000). Recently, this project was downsized due to a lack of funding and the only remaining activity was the maintenance of two transgenic plants in a greenhouse facility at Udayana University. Moreover, the principal investigator does not have any intention of releasing these plants commercially due to difficulties in fulfilling the complex regulatory process and its associated high costs. The result of this project is currently directed toward the development of biopesticides for CPVD, even though the project has generated two patents in Indonesia for two open reading frames (patent number P-00200400345 and P-00200400346).

III.3 Construction of Transgenic Drought-Resistant Sugarcane at PTPN XI, Surabaya

The construction of drought-tolerant sugarcane was started in 1999. The gene, *bet A,* was donated by PT Ajinomoto. It encodes an enzyme

Table 8: Actual and Present Value of Cost of R&D of Citrus Resistance to CVPD at Udayana University

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1997/1998	Gene Isolation, plasmid/vector construction*	143,133	455,947	48.49	122.52
1998/1999	Gene Isolation, plasmid/vector construction*	150,897	407,355	15.28	32.49
1999/2000	Gene Isolation, plasmid/vector construction*	160,059	366,176	20.50	36.99
2000	Plant transformation**	924,269	1,791,953	108.30	202.18
2001	Plant transformation**	1,110,226	1,824,137	108.15	172.45
2002	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	177,481	247,124	19.16	22.50
2003	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	208,441	245,960	24.32	26.25
2004	Confirmation of gene, integration, and gene expression, gene function , phenotype of plant	233,900	233,900	26.03	26.03
	Total Cost	3,108,406	5,572,552	370.23	641.42

Note: (i) Some part research was done (subsidised) in Nagoya University (Japan).
(ii) Research was funded by JSPS (Japan grant).
- Present Value (PV) for 2004, with interest rate of 18 per cent.
- Does not include food safety assessment/analysis.

called *choline dehydrogenase,* which oxidizes *choline* to *glycine betaine.*[7] *Glycine betaine* is an osmo-protectant. The target plants were local sugarcane varieties. Currently, the transformants are maintained through vegetative propagations (stem cuttings) and release approval has already been applied for these. In compliance with the regulation, it underwent evaluations at the containment facility at ICABIOGRAD Bogor in 2003, and confined field tests were also carried out in East Java (Asembagus and Jatiroto). The total budget that has been spent in four years reached IDR 1.3 billion (PV 2004 IDR 2.3 billion), or equal to US $ 154,000 (PV 2004 US $ 255,000). The details can be seen in Table 9.

III.4. Construction of Transgenic Rice Resistant to Stem Borers at the Indonesian Institute of Science

The project was initiated in 1996, funded by grants from the Rockefeller Foundation and the Indonesian Government through APBN. The Rockefeller Foundation sponsored the research from 1996 to 2000. The transgene, *cry* 1A(b), was a gift from Altosar. Research activities began in 1996 with the establishment of tissue culture system, followed by the transformation of rice plants as summarised in Table 10.

IV. The Total Cost to Comply With the Biosafety Requirements for Commercial Releases

IV.1 Government Research Institutions

IV.1.1 Drought-Resistant Transgenic Sugarcane (PTPN XI)

In 2003, PTPN XI registered the transgenic sugarcane to BFSC through BFSTT, to evaluate its phenotype and invasiveness at the containment facility in ICABIOGRAD. Evaluation of the stability of the transgene was simultaneously carried out in greenhouses and laboratories at PTPN XI. Authorisation for the confined field trials were granted by BFSTT in 2003, and was implemented in two locations in East Java (Jatiroto and Asembagus). By 2005, the total expense paid by PTPN XI to fulfill these regulatory requirements was IDR 178 million (Table 11).

IV.1.2. Transgenic Rice Resistant to Stem Borers (Indonesian Institute of Science)

After seven years of development, the resulting transgenic plants were subjected to a confined field trial in 2003. That year, the Bt-rice was

Tabel 9: Actual and Present Value of Cost of R&D of Sugarcane Drought Tolerant at PTPN XI

Yeat	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1999 (Jul-Dec)	Tissue culture system for sugarcane	130.481	370.883	16,71	47,49
2000 (Jan- Jun)*	Plant transformation	773.774	1.079.694	90,67	126,52
2000/2001(Jul-Jun)	Confirmation of gene integration	237.036	468.833	23,09	45,67
2001	Lines selection	143.651	246.917	13,99	24,05
2002	Confirmation of gene expression by in vitro enzymatic analysis	95.417	105.706	10,30	11,41
	Total	1.380.359	2.272.024	154,76	255,14

* In 2000 PT. Ajinomoto sponsored the research avtivity by donating equipments and chemicals valued as around 600 million IDR.

Table 10: Actual and Present Value of Cost of R&D and Regulatory of Bt-Rice, RCB-IIS

Yeat	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(000 IDR)		(000 US $)	
1996	Tissue culture system for rice	352.716	1.257.105	150,284	535,62
1997	Plant transformation and regeneration	393.552	1.185.332	133,317	401,54
1998	Plant transformation and regeneration	633.879	1.763.526	64,190	178,58
1999	Confirmatin of gene integration, expression, and stability of gene integration	492.190	1.143.948	63,028	146,49
2000	Confirmatin of gene integration, expression, and stability of gene integration	633.941	1.285.474	68,571	150,63
2001	Crossing between transgenic Vs popular variety, Gene Stability	202.753	259.079	19,750	25,24
2002	Crossing between transgenic Vs popular variety, Gene Stability	215.980	254.562	23,321	27,49
	Total	2.925.009	7.149.026	522,462	1,466

(i) Does not include food safety assessment/analysis.

Note: - Present Value (PV) for 2005, with interest rate of 18 per cent
- The research was funded by the Rockefeller in the first 5 years apart from Indonesian government funding.

The total budget spent during the seven year bt-rice construction project (1996-2002) was IDR 2.9 billion (PV IDR 7.1 billion), or equal to US $ 522,000 (PV US $ 1.5 million).

Tabel 11: Direct Cost of Drought Tolerance Transgenic Sugarcane Biosafety Regulatory Phase

Activity	Total actual cost (million IDR)	Total PV (million IDR)	Total actual cost (US $)	Total cost PV (US $)
Dossier filling for 1 risk assessment (2003)	4	7,8	470	905
Containment facility Test at ICABIOGRAD (2003)	8	13,1	933	1.534
Gene stability and plant phenotype at PTPN XI' green-house (2003)	50	69,6	5.834	8.123
Confined field trials (plant phenotype, drought tolerance, sugar content etc) in East Java (2003/2004)	58	68,4	6.455	7.617
Confined field trials (plant phenotype, drought tolerance, sugar content etc) in East Java (2004/2005)	58	58,0	5.961	5.961
Sub-total biaya	178	216,9	19.649	24.139
Gene-flow	?			
Non-target spesies	?			
Food safety	?			
Feed safety	?			
Data evaluation	?			
Total	?			

Tabel 12: Direct Cost of Transgenic Rice Resistance to Stemborer Biosafety Regulatory Phase

Activity	Actual Total cost (million IDR)	Total cost PV (million IDR)	Actual Total cost (US $)	PV 2005 (US $)
Dossier untuk pengkajian keamanan hayati	6.0	9.8	650	1,060
Non target impact (serangga pengendali hayati)	60.0	83.5	7,000	9,750
Non target impact (serangga pengendali hayati)	70.0	82.6	7,790	9,190
Non target impact (bakteri tanah)	900	90.0	9,250	9,250
Sub-total	266.0	266.0	24,250	29,250
Gene-flow*	50.0	42.4	5,140	4,350
Uji multi lokasi* (2 musim tanam, 10 unit @ 20 juta rupiah)	400.0	287.3	41,110	29,520
Evaluasi data-data (non-target impact)*	10.0	8.5	1,030	870
Evaluasi data-data (gene-flow)*	10.0	722	1,030	740
Total	696.0	611.3	73,000	64,730

Note: *estimation cost (the activity not yet done).

also registered to get approval for commercial release. The approval process began with an authorization from the BFSC through the BFSTT for conducting confined field trial studies in West Java (held in Sukamandi, Karawang, Pusakanegara, and Indramayu). The field study was carried out in three years to evaluate the effect of Bt toxin carried by the transgenic plants on non-target species, especially insect predators and soil microbes. On 2006, there will be more studies on gene flow from the transgenic rice (Table 12). All the costs listed in Table 12 below were direct costs.

Table 12 shows that up to 2004, IIS had spent IDR 226 million (PV IDR 266 million), which equals US $ 24,200 (PV US $ 29,000). According to Dr. Inez S. Loedin, IIS would need an additional IDR 470 million to complete all the requirements of the approval processes listed in Table 12. That additional fund would be required for gene flow studies, multi-location testing, and for facilitating meetings of BFSTT and the Team for Varietal Release to evaluate the collected data from the aforementioned studies.

IV.2 *Multinational Companies*

IV.2.1 Bt-Cotton Resistant to Bollworm (Monsanto)

Indonesia was the first country in South East Asia that approved commercial field releases of transgenic plants. To obtain a permit to release their Bt-cotton, Monsanto had to comply with the regulatory processes by conducting evaluations and research on Bt-cotton at the containment facility owned by the ICABIOGRAD. The approval for a limited field release at seven districts in South Sulawesi was obtained in 2001. The total to complete the process was approximately IDR 919 million (PV IDR 974 million) of direct cost or approximately US $ 93,000 (PV US $ 99,800), as summarised in Table 13. The time spent on additional research and assessments was merely 2-3 years. It only took less than a year to attain a safe for environment status from the BFSTT, but it took longer to actually get the permit from the BFSC and the Minister of Agriculture. A limited permit was finally issued with the following conditions:

(i) The permit was only valid for one year
(ii) Bt cotton could only be planted at seven districts in the province of South Sulawesi.
(iii) The release must be monitored by an appointed team.
(iv) Harvested seeds and other byproducts must not be used for feed nor food.

Table 13: Direct Cost of Transgenic Cotton Resistance to Cotton Boll worm

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(million IDR)		(US $)	
1998	Dossier for risk assessment	10.0	16.4	1,010	1,660
	Morphological characteristic (containment facility at ICABIOGRAD)	16.0	26.3	1,620	2,660
1999	Confined Field Trials	30.0	41.8	3,840	5,350
2000	Multi-location trials	140.0	165.2	16,400	19,360
	Technical Team meeting fee	10.0	11.8	1,170	1,380
2001	EIA(environment Impact Assessment)-Gene Flow	125.0	125.0	12,180	12,180
	EIA-Non target impact	193.0	193.0	18,800	18,800
	EIA-soil microbes	395.0	395.0	38,480	38,480
Total	919.0	974.5	93,500	99,870	

***Note*:** Present Value (PV) for 2005, with interest rate of 18 per cent.

Table 14: Actual and Present Value of Regulatory Cost of Corn- RR NK603 (Monsanto)

Year	Activity	Actual Total Cost	PV Total Cost	Actual Total Cost	PV Total Cost
		(million IDR)		(US $)	
2002	Dossier for risk assessment	10.0	16.4	1,080	1,770
2002	Morphological characteristic				
	1. Non target impact, invasiveness in contained facilities	16.0	26.3	1,730	2,840
	2. Limited trial at 3 locations	30.0	49.3	3,240	5,320
2002	Dossier for food safety	10.0	16.4	1,080	1,770
2002	technical meeting (twice)	15.0	24.6	1,620	2,660
	Total Expended Cost	**81.0**	**133.1**	**8,750**	**14,370**
	Estimated future expenses :				
?	1. Multi-location trials (10 units, 2 seasons, app 9 million)	180.0	180.0	18,530	18,530
?	2. Variety released Team meeting to evaluate multi-location trials data	15.0	15.0	1,540	1,540
?	3. Confined Field Trials				
	a. EIA-Gene Flow	125.0	125.0	12,870	12,870
	b. EIA-Non target impact	193.0	193.0	19,870	19,870
	c. EIA-soil microbes	395.0	395.0	40,660	40,660
?	4. Feed safety studies (fish, poultry)	15.0	15.0	1,540	1,540
?	5. Additional Technical meeting (3 times)	30.0	30.0	3,090	3,090
TOTAL	**1,034**	**1,086**	**106,850**	**112,480**	

Note : - Present Value (PV) for 2005, with interest rate of 18 per cent.

- ? not yet mentioned.

(v) The permit would be reevaluated if some unintended negative consequences that could harm the environment and human health were found.

In 2001, about 6,639 farmers planted Bt-cotton over a 4,363 hectare area with an average yield of 1.2 tons/hectare. By 2002, the plantation area increased to 5,124 hectares and 10,424 farmers were involved. The average yield also increased to 2.2 tons/hectare, which was 2-3 times higher than the average yield of non-transgenic cotton varieties.[8] However, for some reasons Monsanto decided not to continue the plantation of Bt-cotton in 2003.

IV.2.2 Roundup-Ready NK603 Corn

Monsanto started the application process for the herbicide-resistant corn in 2002. Originally, approval application was made for two roundup-ready corn varieties: RR GA21 and RR NK603. However, Monsanto subsequently decided to focus on RR NK603 for the Indonesian market. Table 14 shows that since 2002 the company has spent around IDR 81 million (PV IDR 133 million), which equals US $ 8,700 (PV US $ 14,000). Until this paper was written, a release permit had not been issued for RR NK603. It is expected that more research and evaluations would need to be carried out to get the approval, which means that around IDR 953 million or US $ 106,000 would be needed to pay for the whole regulatory processes.

Discussions

Based on the tables presented previously, it can be seen that the research cost for constructing and releasing transgenic plants is varied. This variation was caused by differences in the commodities used as the target plants, the trait-introduced, the type of research, the location of the research, the institutions performing the research (government-owned companies, universities, independent public institutions), and the source of funding. Variations can also happen on very similar research projects due to differences in approach, methods, and/or parameters to be studied. Table 15 lists the budget needed for both the construction and approval processes.

Table 15 shows in this case that the construction of transgenic plants required an actual budget of IDR 1.4-3.1 billion (PV IDR 2.4-7.1 billion), which equals to US $ 171,000-522,000 (PV US $ 641,000-1,500,000). These numbers clearly mean that constructing transgenic

Table 15: Estimated Cost for R&D and Biosafety Regulatory of Several Transgenic Crops in Indonesia*

Crop	Year of activity	Initiated step of activity	Present activity status (2004/2005)	Estimated cost			
				Actual (million IDR)	PV (million IDR	Actual (thousand US$)	PV (thousand U$$)
Potato resistance to fungi/ nematode	1994-04	Gene isolation	Green house (plant phenotype dan confirmation of gene integration and expression and function)	1.431	2.470	317,5	650,8
Citrus resistance to CVPD	1997-04	Gene isolation	Green-house (plant phenotype dan confirmation of gene integration, expression, function)	3.108	5.572	370	641
Sugarcane tolerant to drought	1999-02	Plant transfor-mation	Confirmation of gene integration and expression	1.380	2.272	154,76	255,14
	2002-05	Biosafety regulation	Confined field trials (plant phenotype, sugar content, drought tolerance)	178	216,9	19,6	24,1
Rice resistance to stemborer	1996-02	Plant transfor-mation	Confirmation of gene integration, expression, and transformation stability	2.925	7.149	522,5	1,466
	2002-05	Biosafety regulation	Confined field trials for non-target impact (natural enemies and soil microbes)	226	266	24,2	29,25
Bt-cotton	1998-02	Biosafety regulation	Contained facility test (plant morphology), confined field trials, multilocation tests, environment impact assessment (non-target impact-natural enemies, soil microbes)–gene-flow). The transgenic Bt-cotton crop had been released for commercial use in 2001, 2002, but the proponent did not extend the approval or continue bt-cotton business in Indonesia in 2003	919	974,5	93,5	99,9
RR-Corn	2002-02	Biosafety regulation	Containment Facility Test (plant morphology) at ICABIOGRAD, confined field trial in 3 locations, assessment for environment and food safety. Not yet gained the release approval	81	133	8,7	14,4

Note: * Direct cost only.

plants is neither a cheap nor trivial activity. The project can take more than four years just for the construction stage, and further time and resources would need to be allocated to comply with the regulatory procedures to obtain the permit so that farmers can plant these on their fields.

The cost of the regulatory process can be inferred from the case of Monsanto and the Indonesian Institute of Science when they attempted to gain approval for their transgenic plants. Bt-cotton, which is neither a food nor feed crop, had to undergo three years of evaluation with a steep cost of IDR 919 million (equal to US $ 99,000). It is potentially worse for food crops, as in the case of RR NK603 corn. After five years of evaluation for approval that cost IDR 81 million (PV IDR 133 million), it has not even met the requirements set by the BFSC through the BFSTT for its commercial release. It is estimated that IDR 900 million of additional fund would be required for completion of the regulatory procedures. It should be noted that this RR NK603 corn has already been released commercially in several countries, including The Philippines.[9]

The cost of the regulatory processes leading to commercial release of transgenic plants that must be paid by institutions (private and government-owned) in other countries will be described as a comparison. In India, the cost of government approval to release the Bt-cotton (which had already been released in the USA) was US $ 900,000 (excluding salaries). The process took 3-4 years and only consists of additional trials conducted in India. Assessments on transgenic plants that have never been released in other countries would cost more and need a longer period of evaluation. Nevertheless, the cost incurred to government-owned institutions would be lower. It is estimated that the cost of approval for transgenic Bt-eggplant constructed by a government institution would be around US $ 53,000. In the future, releasing transgenic plants in India, like Bt-corn, for example, would cost around US $ 500,000 to comply with the regulatory requirements.[10]

China, on the other hand, is likely to charge less than India. The expenses paid by private companies to gain approval in China were only US $ 65,000 to 89,000, while the government institutions in China would only need US $ 53,000 to 61,000. Only a small fraction of those approval cost were needed for the biosafety evaluation/assessment (around US $ 15,000), while the rest was mainly used for breeding purposes. Meanwhile, the cost of food safety assessment is relatively more expensive. For example, the cost of food safety assessment for transgenic mustard (a close relative of canola) was US $ 3-4 million in the USA and Europe. In China, a similar process carried out on Bt-cotton and Xa-21 rice would cost US $ 600,000 .[11]

It is difficult to make a cost comparison between private companies and the government institutions in Indonesia because there have not been any commercial releases of transgenic plants produced by government institutions. However, some comparisons could be done if we break the regulatory processes down into stages, such as dossier filling. Private companies like Monsanto were expected to pay around IDR 10 million for dossier filling, while government institutions like IIS and PTPN XI are only expected to pay IDR 6 million and IDR 4 million, respectively. For an environmental risk assessment study like the effect of Bt on non-target organisms, IIS only paid IDR 80 million whereas Monsanto had to shell out IDR 193 million. For gene flow studies, IIS also would pay around IDR 80 million compared to Monsanto that had to pay IDR 125 million (Table 16).

For Table 16, we were also attempting to obtain some information/data from several laboratories performing part of the evaluation studies. From our discussion with one of the members of the BFSTT, it was concluded that a standardised test or a minimal requirement system for risk evaluation is definitely required, like the number of samples, replicates, observed parameters, the length of experiment, and the number of seasons over which the experiment should be conducted. Therefore, the result is more universally applicable in deciding the safety issues of the genetically-engineered products.[12]

Like the cost of research in transgenic construction, there is also a significant variation in the cost of the approval process. It depends on whether the applicant is a private company or a government-affiliated institution. This holds true for many countries. The approval cost is also contingent on the number of additional evaluations that need to be carried out in the country where the application is lodged (in-house assessments). There is no available standard for the type of information/data that needs to be supplied in this in-house assessment process, technical and cost-wise. As an example, the following table summarises the type of data that needs to be supplied for risk assessments in other countries.

Table 16: Estimation of the Cost of Some Tests for Risk Assessment (Environment and Food/Feed Safety in Indonesia (in IDR)

Test type	Food analysis lab at BAU	Post Harvest Lab	ICABIOGRAD Biology moleculer' lab	Animal husbandry nutrition lab, BAU	Fish nutrition lab, BAU	Research Institute for Rice- Indon Inst for Scienceb	Gajahmada University, Univ. Hasanudin, BAU, Monsanto
Proximate	390 thousand	140 thousand	80 thousand				
Poultry feeding				1.2 billion			
Goat feeding				1.2 billion			
Cat fish feeding					50 million		
Non-target spesies (serangga)						70-80 million	193 million
Non-target spesies (mikroba tanah)						90 million	190 million
Gene-flow						80 million	125 million

Tabel 17: Type of Data and Experiment Needed for Risk Assessment (Environment, Food, Feed Safety) for Transgenic Crops (Dr. Jose Falck-Zepeda, 2003*)

Data	
Product characterization	Unique identifier, reference material, validation, gene stability, protein purification, mechanism of action, homology, digestability, etc
Food/feed safety	Toxicology (acute and repeated oral, mutagenicity and developmental, sub-chronic and chronic), oncogenicity, effect on immune and endocrine system, dietary characteristic, norwegian rat allergenicity studies, monkey feeding, dog feeding, nutritional value, micotoxin analysis, anti-nutrient
Feeding studies	Poultry, fish, cow, buffalo feeding studies
Compositional analysis	Proximal studies, aminoacid sequence
Ekspression studied	Leaf, stem, floral, seed, oil etc
Environmental safety	Non-target impact (predator, parasites, bee, ants, soil microbes, herbivore, storage pests, weeds), gene-flow (develop model, field studies of pollen flow, development of insect resistance strategy (baseline resistance studies).

Note: *Summary from the questionare template that we used in this survey

There was also no consensus on the number of years and replications of the tests necessary for the risk assessment. The same applies for food safety evaluations. What types of information/data were needed to be supplied? Would the information/data collected from other countries be applicable as well? What conditions are necessary for in-house assessments?

Apart from data that originated from Indonesian researchers and laboratories, we also tried to review the cost of biosafety and food safety assessments in other countries like India and China (Table 18) in order to estimate the necessary costs required to gather the necessary data for the risk assessment process.

Prospects and Challenges for Research, Development, and Application of Transgenic Plants in Indonesia

A continuous expansion of the plantation area of transgenic plants worldwide indicates that there is a significant increase in public

Table 18: Estimation of Cost of Several Test for Risk Assessment in India and China

Type of experiment	Estimated cost (US$)	References
Goat feeding study-90 day	55,000	India (Pray *et al.*, 2005)
Cow feeding study	10,000	India (Pray *et al.*, 2005)
Water buffalo feeding study	10,000	India (Pray *et al.* 2005)
Pollen flow	40,000	India (Pray *et al.* 2005)
Poultry feeding study	5,000	India (Pray *et al.* 2005)
Fish feeding study	5,000	India (Pray *et al.* 2005)
Brown Norway rat allergenicity study	150,000	India (Pray *et al.* 2005)
Socio economic study	15,000	India (Pray *et al.* 2005)
Baseline resistance study	20,000	India (Pray *et al.* 2005)
Limited field trial	5,000	India (Pray *et al.* 2005)
Resistance study	20,000	India (Pray *et al.* 2005)
IPM package	10,000	India (Pray *et al.* 2005)
Food safety-anti nutrients	120	China (Pray *et al* 2006)
Food safety-rat feeeding (90 day)	14,500	China (Pray *et al* 2006)
Environment safety	32,800	China (Pray *et al* 2006)
Environment field trial	1,500-5,000	China (Pray *et al* 2006)

acceptance of transgenic crops. There is also an increase on the number and variety of transgenic plants being constructed and released for commercial applications. This was accompanied by growth in the amount of investments in this field as well. By 2005, a total of 90 million hectares of land in 21 countries was cultivated with transgenics grown by 8.5 million farmers.[13] The number of applications for field trial in several developing countries has also increased. For example, in 1997 China has received 1044 applications for confined field trials and 777 of those were approved, which consisted of 60 different transgenic plants. By 2003, approvals for commercial releases were granted for 30 varieties of Bt-cotton, and this number further increased to 140 in 2004.[14] In the Philippines, four varieties of transgenic corn (NK603, Bt11, Mon810, and NK603xMon810) have been approved for commercial release.[15]

As an agrarian country, Indonesia is keen to implement genetic engineering to further improve the agricultural output and the welfare of its citizen. This is reflected in the willingness of the government to adopt the application of transgenic plants, even though everything was carried out under the principle of cautiousness. In the current era of globalisation, it is difficult to isolate one country's policy from the others. This is even more pronounced under the regime of international conventions like CBD (Cartagena Protocols), GATT, WTO, and others.

Consequently, in order to increase its competitiveness in the global arena, Indonesia needs to put in place a solid research and regulatory system to encourage positive developments and applications of the transgenic plants.

Prospects and Challenges of Research for Constructing Transgenic Plants in Indonesia

Constructions of transgenic plants have been initiated since 1996 in Indonesia. At the same time, regulations on genetically engineered products were also issued. However, the progress of research and applications of transgenic plants in Indonesia has not been as rapid as expected..

Several developing countries have also constructed their own transgenic plants. There have been 209 transformation projects carried out in 76 institutions from 16 developing countries.[16] Like Indonesia, generally these countries initiated the projects at the beginning or middle of the 1990s. Indonesia is one of the most active developing countries in building up its plant genetic engineering programme, with 11 per cent of the total transformation events taking place in its laboratories (209 transformation events). As a comparison, among other most active developing countries, China performed 14 per cent of the transformation events, South Africa did 13 per cent, Argentina 10 per cent, and India also had 10 per cent. However, the success of such programmes would be indicated by the number of transformants that are actually registered for commercial release. In this regard, Indonesia is classified as being not as successful as other countries like China and India. In India, in 2003 commercial release application were made for 34 events, while in that same year the Chinese National Commission of Biosafety received 1044 applications for confined field trials.[17] Meanwhile, there was only one approval issued in Indonesia, and that permit was only valid for one year. The proponent had to renew the permit each year, but after three years elapsed, Monsanto decided not to extend it any further.

Research on transgenic plant constructions in Indonesia during the period of 1996-2004 are listed in Table 6. There were 20 different commodities being targeted for transformation, with several different introduced traits. But they were largely or mostly unsuccessful. Out of 31 different construction activities, only 16 of them were still active (going-on) and only two of these 16 actually resulted in application for for release approval. There were several reasons given by the researchers for these projects being terminated, such as lack of progress; termination of grants; *etc.* It would be interesting to look further into the actual cause of such low success rates of transgenic research in Indonesia. Was it caused by a lack of technology transfer or by a non-conducive research environment? Or was it because of limited and irregular fund availability?

There were several institutions performing transgenic constructions in Indonesia, such as government institutions whose mandate exclusively pertains to conducting research; universities; government-owned corporations; and private companies.[18] Government institutions with exclusive research mandates tend to have an easier time in getting research grants, but this is not the case with the universities, whose main mandate is education. Consequently, most research activities in the universities have a shorter lifespan and rely heavily on competitive domestic grants like RUT and grants from overseas. Once the funding is terminated, research activities associated with it will also cease to exist. A good example, of this unfortunate condition is found to be in the development of citrus resistant to CPVD and potatoes resistant to fungi/nematodes, which were the results of at least five years worth of research that cost between IDR 1.4 - 3.1 billion. These activities were simply terminated, because there was no funding available for the principal investigators to apply for the expensive and complicated regulatory process required for the approval. This clearly set a negative precedent for future developments of transgenic plants. On the other hand, a stringent regulation that complies with international standards is required to ensure the safety and health of the public and the environment. This is an absolute prerequisite in gaining public acceptance of genetically-engineered products, as also in the winning of acceptance from other countries of Indonesian agricultural products with genetic modifications (personal communication with the Director General of Food Crops, 2006). So how thorough should the evaluation process be? What types of tests need to be conducted? And who will foot the bill? These questions need to be considered before starting a research in developing transgenic plants, so that the result of all the hard works can be utilised by farmers and all Indonesian citizens in general.

The results of the surveys also indicate that priorities must be set to decide on which commodities will benefit most from genetic engineering. The priorities can be set by considering all the available information/data, both on technical and socio economical aspects. Socio economic assessment is needed (i) to get real beneficiaries of the transgenic plants; (ii) to get real benefit-cost involve in R&D activities; (iii) to get tolerance level; (iv) as a back up for policy direction on prioritisation; and (v) as a transparency tool for accountability of activities. Once the priorities are set, a commitment needs to be made so that resulting research activities would be guaranteed continuous funding and supportive research environment. The funding and required facilities can be obtained through cooperation with an appointed institution that is both competent and has a strong commitment to produce transgenic plants that can be utilised by farmers and consumers in general.[19]

Prospects and Challenges of the Applications of Transgenic Plants in Indonesia

In order to win public acceptance for transgenic plants and their derivative product for domestic uses or exports, a set of regulations that comply with international standards and guarantee the food, feed, and environmental safety is needed. Several regulations on this matter have been issued in Indonesia, from the ministerial level to Presidential Decrees. The regulations continuously evolved since their inception in 1996, in the form of Food Law and other kinds of regulations, until the publication of Government Regulation No. 28 (2004) on food safety of genetically-modified products and Government Regulation No. 21 (2005) on the biosafety of genetically-modified products.

On a global scale, the existence of regulations on biosafety and food/feed safety in different countries will improve the acceptance of transgenic plants by the majority of the population as long as those regulations have consistent implementation and are strictly enforced. This was partly responsible for significant increase of the plantation area of transgenic plants worldwide. There are several benefits that can be reaped from planting transgenic crops. Available scientific data suggests that transgenic crops have improved agricultural production, increased farmer income, and reduced the usage of pesticides.[20] This can be illustrated by the following points:

1. China has started planting the Bt-cotton since 1997. By 2004, the total plantation area of Bt-cotton has increased to 5.7 million hectares, which is roughly 65 per cent of the total plantation area for cotton. Bt-cotton produced 8-10 per cent more yield compared

to non-Bt cotton. There are also additional savings from reduced insecticide use, which was around US $ 94.10 per hectare. Chinese national income derived from Bt-cotton was US $ 1.1 billion in 2004.

2. Mexico began planting Bt-cotton in 1996. Farmers who planted the cotton gained additional income from US $ 113 per hectare to US $ 354 per hectare compared to farmers who did not plant the Bt-cotton.

In the case of Indonesia, farmers started planting Bt-cotton in seven districts in the Province of South Sulawesi in 2001. Monsanto, as a multinational company, could only obtain a limited permit that had to be renewed each year. However, Monsanto decided to stop selling the Bt-cotton (Bollgard) in 2003 due to various reasons. One among these was that it was not profitable for them. Cotton is one of the major raw materials for the textile industry, but 99 per cent of the domestic requirements for cotton in Indonesia were still imported. A study conducted by Siregar and Kolopaking (2002) showed that the net income of farmers planting Bt-cotton was IDR 1,386,706 per hectare (equal to US $ 138 per hectare) while the net income of farmers planting other varieties of cotton on average was IDR 765,299 per hectare (equal to US $ 76.5 per hectare). The difference extended to the labour used as well; farmers planting Bt-cotton used less labours compared to the farmers planting non-Bt cotton.[21]

The fact that the plantation of Monsanto's Bt-cotton was terminated has impeded the development toward widespread plantation of other genetically-modified plants. Until this paper was written, no other transgenic plants have been commercially released in Indonesia, even though there has been an increase in the type of plants and their area of plantation in neighbouring countries like China, India, and the Philippines.

In order to facilitate and accelerate the development of transgenic technologies in Indonesia, a regulatory apparatus that can be implemented easily, economically, and consistently is required so that public acceptance of transgenic plants can be further improved. A simple legal framework is essential and necessary. However, the regulation has to be based on an international standard, be founded on a solid scientific basis, and should be accompanied by clear operational and technical guidance so that it can be easily implemented. The regulation would be implemented by the Biosafety and Food Safety Commission

(BFSC) and BFSTT. The organisation should be composed of experts and decision makers from several government institutions and private sectors. The system/framework of the commission must be clearly defined to prevent it from impeding the implementation of the regulations. This study found that under the old regulation (the joint ministerial decree), the BFSC's membership consisted of 21 high-ranking government officials, who due to their busy schedules always had difficulty in scheduling a meeting among them. Since its inception, the BFSC has only held 3-4 meetings. The BFSC was assisted by the BFSTT in their decision-making processes. But actually, it was the BFSTT who ran the day-to-day operation of the regulatory system. The BFSTT is an *ad hoc* committee, whose membership consisted of experts from different scientific backgrounds. It does not have a full time secretary for its daily operations. Its activities are scheduled according to the number of applications received by the technical team, and are mostly funded by the proponent/applicants. Each member of the BFSTT also had many other commitments so they often had difficulties in attending to their duties as Member of the Biosafety and Food Safety Technical Team. To illustrate this, it took the BFSTT less than one year to give approval to Monsanto's Bolgard cotton, but it took more than two years for the BFSC and the Minister of Agriculture to issue the permit even though the plant in question had already been certified as safe by the BFSTT.

This study also found that the BFSTT has not issued a standard (a SOP) on what kind of tests would need to be performed for evaluating the release of transgenic plants. For example, is it really necessary for different types of transgenic plants like the drought-resistant sugarcane (PTPN XI), Bt-rice resistant to stem borer (IIS), and potatoes resistant to fungi/nematodes (BAU) to supply all the information/data listed in Table 17?

Any existing regulations must clearly state whether data on food safety obtained overseas was also applicable in Indonesia, so that transgenic plants that have been released in other countries no longer need to be subjected to in-house data collections. Similarly, what kind of environmental impact assessment was necessary for plants that have been released in other countries and those that have never been released anywhere in the world? What kinds of parameters need to be measured in an environmental impact assessment? The applicants can carry out a food safety and biosafety evaluation according to the requirements set by the law/regulation once these issues are clear so that, there will not be any dispute or ambiguity when the information/data obtained from the evaluation process does not meet the required standards. For example, in an impact study on non-target insects, what kind of non-target insects would need to be evaluated? Or which soil would microbes need to be studied? Such details would need to be worked out because they would influence the cost of the approval process (without any disregard to the scientific/evaluative aspects). Ideally, the only information/data that need to be gathered in-house are those that have not been evaluated anywhere else, while data that are already available should not be gathered by *in-house* experiments. Any additional in-house experiments that may need to be performed should be done to answer standard questions set by the regulations for commercial release.

Endnotes

[1] James (2003).
[2] ISAAA (2005).
[3] Moeljopawiro and Falconi (1999); Bahagiawati *et al.* (2003).
[4] Pray *et al.* (2005; 2006).
[5] Moeljopawiro and Falconi (1999); Bahagiawati *et al.* (2003).
[6] Wirawan IPG (2000; 2004).
[7] Murdiyatmo *et al.* (2004).
[8] Bermawie *et al.* (2003).
[9] Halos (2006).
[10] Pray *et al.* (2005).
[11] Pray *et al.* (2006).
[12] Dedi Fardiaz (2006), personal communication).
[13] ISAAA (2005).
[14] Pray *et al.* (2006).
[15] Halos (2006).
[16] Atanassov *et al.* (2004).
[17] Pray *et al.* (2006).
[18] Moeljopawiro and Falconi, (1999); Bahagiawati *et al.* (2003)
[19] Personal communication with the Director General of Horticultures, 2006.
[20] Graham and Barlofoot (2005).
[21] Lokollo (2001).

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The *Asian Biotechnology and Development Review* (*ABDR*) will shortly celebrate its 10th anniversary. Since its inception, the Review has provided an excellent platform for bringing the focus onto themes of major concern for Asia in the field of biotechnology. It has served to inform institutions in Asia and also the UNESCO Microbial Resources Centres (MIRCEN), worldwide, on the development of biotechnology within the Asian region and has been a valuable and reliable resource for these institutions. It has given visibility to biotechnology research, development and progress in Asia and played a role in leveraging scientific knowledge for the benefit of scientists in the region. It has been important in bringing together the scientific and policy perspective on various important issues like IPR, biosafety and regulatory issues, etc. The objectives of the *Review* fit well with the overarching objective of UNESCO's Natural Science Sector of mobilizing science knowledge and policy for sustainable development. In this context UNESCO has maintained a keen interest in the activities of the Research and Information System for Developing Countries (RIS), in particular the *Asian Biotechnology and Development Review* (*ABDR*). UNESCO maintained a presence for many years on the Editorial Board of the *ABDR*, through the person of Dr. Edgar J. DaSilva.

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